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**14. ABSTRACT**

This grant prepares DANA (Defense Automated Neurobehavioral Assessment), the next-generation neurocognitive assessment tool (NCAT), for transition into operational military use. DANA is a clinical decision support tool developed for and funded by the Department of Defense (DOD) for use in field and clinical settings. The effort is organized around two foci – **science** and **transition**. The science concentrates on CONUS-based studies such as testing DANA in clinical drug, fatigue/alertness, concussion and/or depression protocols. The second thrust, transition, includes obtaining FDA clearance for DANA (DOD has determined it is a medical device), and positioning DANA to be operationally deployed into the military.

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## Introduction

This 24-month effort will assist in the preparation and transition of DANA (Defense Automated Neurobehavioral Assessment), the next-generation neurocognitive assessment tool (NCAT), into operational military use, as well as prepare DANA for use in CONUS clinics. DANA is a clinical decision support tool developed for and funded by the Department of Defense (DOD) for use in field and clinical settings.

The effort is organized around two foci – **science** and **transition**. While the original proposal called for a scientific thrust that would track a deployed battalion OCONUS longitudinally over time, MRMC leadership (Colonels Castro and Hack) agreed that the statement of work be modified to concentrate on CONUS-based studies such as testing DANA in clinical drug, fatigue/alertness, concussion and/or depression protocols. The second thrust, transition, includes obtaining FDA clearance for DANA (DOD has determined it is a medical device), and positioning DANA to be operationally deployed into the military.

**Body: Brief Overview of Progress to Date**

Following the kickoff of the DANA RIF project at MRMC, ATinc convened a Scientific Advisory Panel meeting in Silver Spring, MD where various customers, stakeholders and scientists reviewed the feasibility studies that preceded the current grant (and are summarized in a Military Medicine article in Appendix A) as well as the proposed direction of research in the current effort. Slides from this meeting are attached in Appendix B.

We held multiple meetings with Dr. Laura Brosch, LTC Shoemaker, LTC Atchison, and Ms. Andrea Klein to discuss requirements for IRB approval. Initially an umbrella protocol was discussed with subsequent refining for successive studies, but this was rejected in favor of separate IRB protocols for each study.

The original SOW was approved, and protocols for the research studies were submitted for IRB approval.

In each of our studies, we are partnering with another organization, and as the data will be collected at that partner's facility, and under their administration, each host is required to submit the specific protocol for that study to his/her respective IRB. Once the study-specific IRB had approved the protocol, we submitted it to MRMC for Army IRB approval. To date, we have obtained approval for the Depression Study at Johns Hopkins Hospital and the PTSD Study with the VA in Hawaii. An amended protocol for the Concussion Study with the Medical College of Wisconsin and University of Wisconsin is to be submitted in January 2014 to MRMC for approval. Data collection for both the PTSD and Depression studies has begun.

We considered a few other studies, e.g., a joint biomarker study with Banyan Biomarker, a sleep deprivation study with WRAIR, and a drug intervention study with NICoE, but when it became apparent that the time needed to obtain IRB approval and other logistical constraints would prevent us from gathering subject data in time for successful completion within the contract period of performance, we decided to omit them from consideration.

In preparation for data analysis, we have extensively reviewed the literature for best-of-breed analysis techniques. This has included the neurocognitive literature as well as other

human performance domains, e.g., sports and movement science. Of critical importance for the DANA assessment tool is the issue of reliability, and during the course of our literature review, we discovered that previous studies, using comparable assessment techniques, reported reliability using methods that were inappropriate to the study design and that inaccurately described the reliability of the test. We have a paper in preparation laying out the issues and their remediation, and intend to incorporate this reliability analysis of the data once collection is complete. See Appendix C for the draft paper in preparation

In a related effort, we are working with Neurocognitive Assessment, Rehabilitation and Reintegration Product Line, UNITED STATES ARMY MEDICAL COMMAND, to collect DANA data from reference populations to provide a device-resident database with which to compare subject data. To date, more that 700 subjects' data has been collected with the project ongoing until all the cells, e.g., women ages 35-64, have sufficient entries. Table 1 shows the number of entries in each reference group to date.

| Age Range | Gender | | Total |
|---|---|---|---|
| 18-19 | M | 101 | 114 |
| | F | 13 | |
| 20-24 | M | 100 | 185 |
| | F | 85 | |
| 25-29 | M | 100 | 137 |
| | F | 37 | |
| 30-34 | M | 76 | 97 |
| | F | 21 | |
| 35-44 | M | 84 | 98 |
| | F | 14 | |
| 45-54 | M | 50 | 57 |
| | F | 7 | |
| 55-64 | M | 22 | 24 |
| | F | 2 | |
| **Total Males** | 533 | | |
| **Total Females** | 179 | | |

**Table 1 Number of Subjects in Reference Groups**

In anticipation of a successful transition to DOD, and without knowing the ultimate user population, e.g., clinician, field medic, researcher etc., we have developed a generic report (see Appendix D) that can be tailored for a specific user. As soon as a defined transition customer is identified, this report will be modified and integrated into DANA.

In order for DANA to transition for use by the DOD, it needs to be reviewed and cleared by the FDA as a mobile medical device. To that end, we submitted a 513(g) application to the FDA requesting determination as to its classification, i.e., Class I, II or III in April 2013. Numerous clarification discussions have ensued, and a decision should be rendered in January 2014. We will then submit a 510(k) Premarket Notification to FDA, seeking

authorization from the FDA that DANA is safe and effective, and ready to transition to DOD. As partial fulfillment of the 510(k), we have prepared documents demonstrating our adherence to Quality System Regulations (QSR), examples of which are found in Appendix E. Similarly, the most current version of the DANA Users Guide is included in Appendix F.

In addition, we have conducted a government-wide market survey and identified a list of potential opportunities for transition within DOD and the Intelligence Community. These are presented in Appendix G.

**Key Research Accomplishments**

While we are only in the initial stages of data collection in two of the three studies proposed, the following milestones have been accomplished –

- Agreement from Scientific Advisory Board regarding research plan
- IRB approvals for two of the three study protocols, with the third approval pending
- Detailed plan for data analysis once collection complete
- Near complete reference group database
- Pending FDA 513(g) determination of mobile medical device classification
- Comprehensive market survey

**Reportable Outcomes**

Since data collection is in progress, there are as yet no research result outcomes to report. However the following significant outcomes are noted –

- Three new research batteries for each of the science studies were compiled. This included the implementation of a new finger-tapping task for the Depression Study at JHU, as well as additional, new surveys.
- Similarly, a unique battery was compiled for the Neurocognitive Assessment, Rehabilitation and Reintegration Product Line, UNITED STATES ARMY MEDICAL COMMAND to collect reference group data from active military personnel.
- A comprehensive database framework has been developed and populated with DANA data collected to date. This will facilitate data analysis and reporting once data collection from the three science studies is complete.
- Automated cleaning and analysis algorithms have been developed and tested in anticipation of the large amount of data to be collected from the three research studies.

**Conclusions**

Unanticipated delays in gaining IRB approval have resulted in a late start to data collection, but two of the three studies are now underway, and the third is soon to begin. Transition continues to be a challenge, both in terms of identifying a transition partner, and getting DANA classified by FDA, necessary first steps in DOD's acquisition process. In parallel, however, we are proceeding to follow up with potential partners identified in the market survey, and are engaged with USAMMAA to understand and navigate the DOD's acquisition and transition process as we proceed.

## References

Lathan C, Spira JL, Bleiberg J, Vice J, Tsao JW. Defense Automated Neurobehavioral Assessment (DANA)-psychometric properties of a new field-deployable neurocognitive assessment tool. *Mil. Med.* 2013; **178** (**4**): 365–71.

## Appendices

A. Military Medicine Reprint

B. Scientific Advisory Board Meeting 110912

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**MILITARY MEDICINE,** 178, 4:365, 2013

# Defense Automated Neurobehavioral Assessment (DANA)—Psychometric Properties of a New Field-Deployable Neurocognitive Assessment Tool

*Corinna Lathan, PhD*; James L. Spira, PhD, MPH†; Joseph Bleiberg, PhD‡; Jack Vice*; CAPT Jack W. Tsao, USN§*

**ABSTRACT** The Defense Automated Neurobehavioral Assessment (DANA) is a new neurocognitive assessment tool that includes a library of standardized cognitive and psychological assessments, with three versions that range from a brief 5-minute screen to a 45-minute complete assessment. DANA is written using the Android open-source operating system and is suitable for multiple mobile platforms. This article presents testing of DANA by 224 active duty U.S. service members in five operationally relevant environments (desert, jungle, mountain, arctic, and shipboard). DANA was found to be a reliable instrument and compared favorably to other computer-based neurocognitive assessments. Implications for using DANA in far-forward military settings are discussed.

## INTRODUCTION

In January 2009, the U.S. Navy Bureau of Medicine and Surgery identified a need to enhance existing battlefield concussion assessment and requested the development of a durable, portable, and field-hardened neurocognitive assessment tool (NCAT) to provide a practical means to conduct neurocognitive and psychological assessment in field deployment settings. The purpose of combining neurocognitive and psychological assessment was to permit more comprehensive evaluation of the broad range of problems that may be encountered during combat deployment. This article describes the resulting NCAT, Defense Automated Neurobehavioral Assessment (DANA); DANA's psychometric properties based on assessment of 224 active duty U.S. service members under challenging field conditions; and presents comparisons to published NCAT data.

DANA consists of three test batteries of different durations and compositions designed for increasingly detailed assessment (Table I). The three batteries include (1) DANA Rapid, a 5-minute battery of three basic reaction-time measures; (2) DANA Brief, a 15-minute test that includes DANA Rapid plus additional neurocognitive tests as well as psychological screening tools for post-traumatic stress disorder (PTSD), depression, and insomnia; and (3) DANA Standard, a 45-minute more comprehensive battery of neurocognitive and psychological tests. This hierarchical set of batteries is designed to facilitate health care providers' access to standardized, reliable, and valid objective and subjective measures. DANA's portability, multiple test batteries, and user-friendly interface enable its use by a wide range of health care providers, from frontline medics/corpsmen to licensed health care professionals.

Establishing reliability and feasibility of this platform in a military population is necessary before attempting clinical validation and utilization. The eventual goal of DANA is to assist clinicians to (a) make rapid and accurate assessment of cognitive and psychological dysfunction secondary to brain injury and/or the psychological wounds and stressors of war,

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The preliminary data of this article, "Defense Automated Neurobehavioral Assessment (DANA): A Field-Deployable Tool for Assessing Concussion and Deployment Stress," was presented as an oral presentation by the authors J.L.S., C.L., J.B., and J.W.T. at the Military Health System Research Symposium (MHSRS) Conference, Fort Lauderdale, FL, August 2012.



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**TABLE I.** DANA Test Batteries*

| DANA Rapid (5 Minutes) | DANA Brief (15 Minutes) | DANA Standard (45 Minutes)** |
|---|---|---|
| Simple Reaction Time (SRT) | SRT | SRT |
| Procedural Reaction Time (PRO) | Code Substitution Simultaneous (CDS) | CDS |
| Go/No-Go (GNG) | PRO | PRO |
| | Spatial Discrimination (SPD) | SPD |
| | GNG | GNG |
| | Code Substitution Delayed (CDD) | CDD |
| | SRT | Matching to Sample (MSP) |
| | Patient Health Questionnaire (PHQ) | Sternberg Memory Search (STN) |
| | Primary Care PTSD Screen (PC-PTSD) | SRT |
| | Insomnia Screening Index (ISI) | Combat Exposure Scale (CES) |
| | | PHQ |
| | | Pittsburgh Sleep Quality Index (PSQI) |
| | | PTSD Checklist—Military Version (PCL-M) |
| | | Deployment Stress Inventory (DSI) |

*For detailed test descriptions, see Table AI. **MSP and STN were still under development at the time of this testing and so are not included in the results.

(b) facilitate referral to treatment for wounded service members, (c) monitor recovery, and (d) aid in return-to-duty determination. Thus, DANA is intended to enhance military capability and better ensure a healthy fighting force.

## METHODS

### *DANA Platform*

DANA is a Java-based mobile application that runs on an Android operating system. The primary advantages of Android are that it is open source, open license (Apache 2.0), well supported and based on a Linux kernel, which is nearly ubiquitous. Java has the advantage of being a high-level, class-based, object-oriented language designed as a "write once, run anywhere" solution and thus is portable across a wide range of devices and desktops. DANA, therefore, can run on any Android mobile device and can be used with a stylus or touch screen.

Based on the Navy Bureau of Medicine and Surgery, requirements for MIL-SPEC commercial-off-the-shelf hardware, we conducted a comprehensive trade study and selected the Trimble Nomad, the military-grade-hardened handheld computer used in the current study. A Tektronix 100 MHz analog to digital (ADC) oscilloscope was used to test the input variability of device hardware and device software that could contribute to the overall response times. A push action switch was connected to the ADC, which was then used as the input stylus on the Nomad to measure RT. The interval between two inputs as recorded by DANA and by the ADC was compared over 10 trials. The average difference was 6.8 milliseconds with a standard deviation (SD) of 3.7 milliseconds. By comparison, the input variability with a Microsoft windows personal computer can range from 4–25 milliseconds.[1,2]

### *DANA Test Battery*

Selection of the neurocognitive and psychological tests included in DANA was established by a tri-service, Veterans Administration, and civilian scientific advisory board that included military and civilian neuropsychologists and psychologists, neurologists, and corpsmen. All tests included in DANA's test batteries meet the requirements of the American Psychological Association's standard for tests and measurements and all tests are in the public domain. Eight cognitive tests and seven psychological questionnaires were selected (Table AI) and are divided into three test batteries, as shown in Table I. Tests were selected based upon their potential to address specific deployment-related concerns, such as concussion and combat distress or exhaustion. Although all tests utilized have an extensive literature regarding their reliability and validity, they have not been reported in this specific configuration nor implemented for service members in this manner. The advisory board also contributed to and provided feedback on the user interface design to ensure ease of use by multiple levels of caregivers including the corpsmen, general medical officers, and neuropsychologists.

### *Participants and Procedure*

To evaluate the deployment feasibility of DANA, we recruited 224 active duty service members comprising 40 or more active duty military personnel in each of 5 diverse operational environments. No subjects were excluded, since all service members were fit for duty, not undergoing any disability evaluation, and thus assumed to be healthy. The purpose of assessing service members across diverse environmental conditions was to show the robustness of the hardware and software administration under different operational tempos and to identify any environmental concerns with the reliability of the instrument.

- — Arctic (Thule Air Force Base—Greenland in the winter)
- — Jungle (U.S. Marine Corps Jungle Warfare Training Center—Okinawa, Japan, in the summer)
- — Altitude (U.S. Marine Corps Mountain Warfare Training Center—Bridgeport, CA, approximately 3,000 m)
- — Desert (U.S. Marine Corps Desert Warfare Training Center—Twentynine Palms, CA, in the summer)
- — Shipboard (USS George Washington during high seas in the Western Pacific)

Device performance (e.g., battery life, display characteristics) was evaluated under the specific environmental conditions (e.g., humidity, temperature) through a minimum of 12-hour exposure. The only instrumentation reliability issue was a screen refresh rate delay in the Go/No-Go (GNG) test in the arctic environment. Because this screen rendering delay would affect test results, the rendering process software was redesigned, which successfully mitigated the delay.

The research protocol was approved by the AnthroTronix Institutional Review Board, the VA Institutional Review Board, and received a Department of the Navy Human Research Protections Program review. A letter was obtained from the commanding officer of each test facility and all subjects signed an informed consent document to participate in testing. On Day 1, each subject was tested on all three batteries, the DANA Rapid, Brief, and Standard. Subjects returned on Day 2 to repeat the sequence of batteries resulting in the following protocol:

— Day 1 (approximately 120 minutes)—Consent Process, DANA Rapid, DANA Brief, DANA Standard
— Day 2 (approximately 40 minutes)—DANA Rapid, DANA Brief, DANA Standard (cognitive tests only)

(The above times include 5-minute breaks between each battery.)

A research team of clinical psychologists and technical staff administered testing. Participants were instructed to hold the stylus about 1-cm above the screen, and to respond as rapidly and accurately as possible. All other instructions were embedded within the tests. To minimize learning and practice effects, test stimuli are generated at random and each test has practice trials before the actual test trials. Parameters of the final version of DANA's individual subtests are described in Table AII including each subtest's stimulus presentation duration, response interval, and interstimulus interval.

Data were analyzed in SPSSv20 for descriptive statistics, split-half reliability, test–retest reliability, and cross-test correlations. For internal consistency, we examined split-half correlations of the first and second half set of trials for the first administration of each test on each day. To evaluate test–retest reliability across administrations, we calculated intraclass correlation coefficients (ICCs)[3] that have been used to evaluate reliability for other health status instruments.[4] Because of multiple analyses, significance levels were set to between $p < 0.01$ and $p < 0.001$, depending upon the number

**TABLE II.** Descriptive Statistics for all DANA Variables for Each Administration

| | Task | Administration | *n* | Median RT Correct ± SD | | Average of Median Throughput ± SD | | Percentage Correct ± SD | |
|---|---|---|---|---|---|---|---|---|---|
| 1 | SRT | 1 | 223 | 309.7 | ±65.3 | 199.6 | ±33.4 | 99.7 | ±3.3 |
| | | 2 | 223 | 309.3 | ±64.6 | 199.8 | ±34.6 | 99.5 | ±2.6 |
| | | 3 | 220 | 300.6 | ±55.5 | 204.4 | ±33.8 | 99.4 | ±3.4 |
| | | 4 | 213 | 302.0 | ±53.3 | 202.2 | ±33.4 | 99.3 | ±4.0 |
| | | 5 | 212 | 308.3 | ±65.1 | 200.6 | ±36.7 | 99.3 | ±4.7 |
| | | 6 | 172 | 298.4 | ±68.5 | 207.1 | ±31.7 | 99.7 | ±2.4 |
| | | 7 | 172 | 307.8 | ±77.0 | 202.1 | ±35.7 | 99.4 | ±2.3 |
| | | 8 | 164 | 305.1 | ±49.2 | 200.7 | ±30.6 | 99.6 | ±2.2 |
| | | 9 | 122 | 317.9 | ±69.0 | 195.7 | ±37.5 | 99.7 | ±1.5 |
| | | 10 | 121 | 310.7 | ±54.9 | 197.8 | ±30.7 | 99.8 | ±0.8 |
| 2 | PRO | 1 | 224 | 604.5 | ±101.6 | 100.1 | ±15.5 | 98.3 | ±4.3 |
| | | 2 | 220 | 579.6 | ±91.4 | 103.8 | ±15.1 | 98.1 | ±4.0 |
| | | 3 | 213 | 571.8 | ±84.8 | 104.8 | ±14.2 | 98.0 | ±4.0 |
| | | 4 | 174 | 579.1 | ±79.9 | 103.6 | ±13.4 | 98.3 | ±3.1 |
| | | 5 | 164 | 579.7 | ±95.4 | 104.1 | ±15.6 | 98.2 | ±3.5 |
| | | 6 | 122 | 565.0 | ±84.1 | 105.7 | ±15.0 | 97.6 | ±5.3 |
| 3 | GNG | 1 | 214 | 535.4 | ±96.8 | 114.2 | ±18.5 | 99.1 | ±2.5 |
| | | 2 | 214 | 519.3 | ±86.8 | 117.6 | ±18.5 | 99.3 | ±2.3 |
| | | 3 | 193 | 520.0 | ±91.4 | 116.7 | ±19.9 | 98.2 | ±4.5 |
| | | 4 | 163 | 527.2 | ±97.4 | 116.1 | ±19.2 | 99.0 | ±2.8 |
| | | 5 | 99 | 506.4 | ±98.3 | 120.9 | ±20.8 | 98.8 | ±3.6 |
| | | 6 | 75 | 521.0 | ±109.6 | 117.7 | ±21.7 | 98.4 | ±5.2 |
| 4 | SPD | 1 | 221 | 1690.2 | ±376.3 | 34.4 | ±7.1 | 92.8 | ±5.4 |
| | | 2 | 209 | 1533.0 | ±361.5 | 37.3 | ±9.4 | 90.6 | ±5.7 |
| | | 3 | 172 | 1562.3 | ±383.9 | 37.8 | ±9.6 | 93.1 | ±5.8 |
| | | 4 | 119 | 1456.6 | ±311.4 | 38.2 | ±7.4 | 89.3 | ±6.2 |
| 5 | CDS | 1 | 223 | 1284.9 | ±277.7 | 47.5 | ±9.5 | 97.5 | ±3.1 |
| | | 2 | 212 | 1256.7 | ±234.5 | 47.8 | ±8.9 | 96.8 | ±4.0 |
| | | 3 | 171 | 1228.7 | ±257.0 | 49.8 | ±10.8 | 97.7 | ±3.1 |
| | | 4 | 120 | 1193.4 | ±211.1 | 50.5 | ±9.4 | 97.3 | ±3.2 |
| 6 | CDD | 1 | 212 | 1046.7 | ±221.5 | 55.0 | ±11.9 | 92.1 | ±8.2 |
| | | 2 | 190 | 1004.3 | ±183.1 | 56.2 | ±11.7 | 91.1 | ±9.1 |
| | | 3 | 161 | 996.7 | ±184.2 | 56.8 | ±12.8 | 90.9 | ±9.5 |
| | | 4 | 103 | 956.9 | ±157.4 | 59.6 | ±11.5 | 92.5 | ±7.9 |

**TABLE III.** Comparison to Previously Reported Data[a]

| | | DANA | ANAM (2006) | ANAM (2008) | ANAM (2012) |
|---|---|---|---|---|---|
| SRT | *n* | 223 | 2,261 | 5,237 | 107,413 |
| | Mean[a] | 309.7 | 261.3 | 267 | 261 |
| | SD | 65.3 | 56.1 | 74 | 47 |
| | Ratio | 21.08% | 21.47% | 27.72% | 18.01% |
| PRO | *n* | 224 | — | — | 107,353 |
| | Mean[a] | 604.5 | — | — | 592 |
| | SD | 101.6 | — | — | 90 |
| | Ratio | 16.81% | — | — | 15.20% |
| CDS | *n* | 223 | 2,331 | 5,237 | 107,546 |
| | Mean[a] | 1284.9 | 1,191 | 1,096 | 1,162 |
| | SD | 277.7 | 248.7 | 265 | 272 |
| | Ratio | 21.61% | 20.88% | 24.18% | 23.41% |
| CDD | *n* | 212 | 1,891 | 5,202 | 107,523 |
| | % Accuracy | 92.1 | 88.7 | 86.30 | 90 |
| | SD | 8.2 | 9.3 | 15.80 | 11.4 |
| | Ratio | 8.90% | 10.48% | 18.31% | 12.67% |

[a]Medians are shown for DANA.

of analyses conducted to correct for type-1 error. Psychological measures were scored using conventional methods.

## RESULTS

DANA performed well in all five field environments with no significant difference across data sets; therefore, the data for all five operational environments were combined. The number of total subjects for each test ranged from $n = 75$ to $n = 224$ depending on whether or not the service member was available to participate in all administrations across 2 days. All but one test (Code Substitution Delayed [CDD]) had over 200 subjects for at least two test administrations.

Scores on psychological measures revealed an overall psychologically healthy sample. Combat Exposure Scale (CES) was in the light range (3.7, with 17 indicating moderate exposure). PTSD Checklist—Military Version (PCL-m) (26), Patient Health Questionnaire (PHQ)-8 (4.6), Pittsburgh Sleep Quality Index (PSQI) (5.9), and Deployment Stress Inventory (DSI) (9.7) were each far below the score needed to reach clinical criteria.

Data exclusions included the elimination of trials with anticipatory responses and test administrations indicating random responses (criterion for exclusion was set at less than 65% correct—since tasks are binary, 50% correct represents random responding). No slow RT responses were eliminated, but to mitigate their undue influence we used medians rather than means to describe the data. Less than 1% of the response trials and less than 2% of the test administrations were eliminated based on these criteria. No subjects were eliminated from analysis based upon a criterion of having more than one test administration eliminated in a battery.

Table II shows the descriptive data for each administration of each test, and Table III compares DANA median RT and SD to previously published reports of mean data from the Automated Neuropsychological Assessment Metrics (ANAM, currently used by the U.S. Department of Defense for baseline, predeployment neurocognitive testing) in military personnel.[5–7] DANA uses median correct RT as the relevant metric, whereas ANAM reports means; however, because of the sample size and the normal populations assessed, the mean and median are assumed to be similar for ANAM.

Although not significantly different, absolute RT values may be different because of differing instrumentation (stylus versus mouse button) between ANAM and DANA. It is also possible to use the published ANAM data to calculate Coefficients of Variation (CVs) (ratio of RT to SD of RT) to show stability[8] and these are compared to analogous DANA subtests in Table III.

For reliability within administrations, split-half correlations of the odd–even trials are reported for the first administration of day 1 and day 2 for each test. Correlations were acceptably high ($p < 0.001$) and generally above 0.85—Simple Reaction Time (SRT) (0.91, 0.93), Procedural Reaction Time (PRO) (0.87, 0.86), GNG (0.85, 0.85), Code Substitution Simultaneous (CDS) (0.94, 0.93)—except for Spatial Discrimination (SPD) (0.76, 0.76) and CDD (0.76, 0.82). For test reliability across administrations, the ICC was calculated. The ICC for SRT was 0.95 indicating excellent reliability across the 10 administrations over 2 days. For PRO, GNG, SPD, and CDS, similar reliability was achieved with ICC values of 0.91, 0.95, 0.89, and 0.88, respectively. Only the CDD test did not have high reliability (0.54), which is expected for repeat CDD tests within a short time period because of the change in codes with each administration, resulting in proactive memory interference.

Correlations were also conducted between all psychological and cognitive measures. With the exception of CDD (difficulties using multiple administrations of this subtest because of memory interference were noted above), all cognitive subtests ($p < 0.001$) and psychological tests ($p < 0.001$) were correlated with each other; however, the psychological and cognitive tests did not correlate with each other in this

**TABLE AI.** DANA Test Descriptions

| Test Name (Abbreviation) | Task Structure | Task Purpose |
|---|---|---|
| Simple Reaction Time (SRT)[a–c] | The subject taps on the location of the yellow asterisk symbol as quickly as possible each time it appears. | This task measures pure RT. |
| Procedural Reaction Time (PRO)[a–c] | The screen displays one of four numbers for 3 seconds. The subject presses on a left button ("2" or "3") or right button ("3" or "4") depending upon the number pressed. | A choice RT measure of accuracy, RT, and impulsivity. This choice RT task targets simple executive functioning with easy decision-making capabilities. |
| Go/No-Go (GNG)[a–c] | This is a forced choice RT task relevant to warfighters. A house is presented on the screen with several windows. Either a "friend" (green) or "foe" (white) appears in a window. The respondent must push a "fire" button only when a "foe" appears. | A choice RT measure of sustained attention and impulsivity. The test assesses speed and accuracy of targets, omissions, and commissions. |
| Spatial Discrimination (SPD)[b,c] | Pairs of four-bar histograms are displayed on the screen simultaneously, and the subject is requested to determine whether they are identical. One histogram is always rotated either ±90 degrees with respect to the other histogram. | Assesses visuospatial analytic ability. |
| Code Substitution Simultaneous (CDS)[b,c] | Subjects refer to a code set of 9 symbol-digit pairs that are shown across the upper portion of the screen. A sequence of single symbol-digit pairs is shown below the key, and the subject indicates whether or not the single pair matches the code by pressing Yes or No. | Assesses visual scanning and attention, learning, and immediate recall. |
| Code Substitution Delayed (CDD)[b,c] | After a delay of several intervening tests, the same symbol-digit pairs are presented without the code. The subject indicates whether or not the pairing was included in the code that was presented in the earlier code substitution learning section. | Assesses learning and short-term memory. |
| Sternberg Memory Search (STN)[c] | The subject memorizes a set of five letters, after which letters appear on the screen one at a time, and the subject determines if the letter on the screen is a member of the memory set. | Assesses working memory. |
| Matching to Sample (MSP)[c] | A single 4 × 4 checkerboard pattern is presented on the screen for brief study period. It then disappears for 5 seconds, after which two patterns are presented side-by-side. The subject indicates which of these two patterns matches the first. | A measure of short-term memory, attention, and visuospatial discrimination. |
| Insomnia Screening Index (ISI)[b] | A 5-item scale evaluating perceived insomnia severity and sleep habits. Each item is rated on a 5-point scale (0–4). | The total score ranges from 0 to 28 and higher scores indicate more severe insomnia. A cutoff score of 10 has been shown to indicate insomnia.[11] |
| Primary Care PTSD Screen (PC-PTSD)[b] | Four screening questions designed for use in clinical settings to screen for PTSD, with 3 out of 4 endorsed items suggestive of likely PTSD. | Questions assess hyper-arousal, re-experiencing, and avoidance for PTSD screening. This test is more sensitive than specific, but correlates highly with the PCL.[12,13] |
| Patient Health Questionnaire (PHQ)[b,c] | A 9-item depression scale assessing symptom severity and diagnostic criteria for major depressive disorder. For research purposes, item no. 9 (concerning suicide) was not included, yet research indicates that the scoring, reliability, and clinical validity are almost identical. | A score of 0–9 is likely to have no depression, 10–14 mild depression, 15–19 moderate depression, and 20+ severe depression.[14] |
| Pittsburgh Sleep Quality Index (PSQI)[c] | 19 self-rated items and 5 partner-rated items, which measure sleep quality during the previous month. This scale differentiates "good" from "poor" sleepers based on seven areas: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction over the last month. | This scale is the most widely utilized sensitive and specific self-report measure for insomnia. A score above 6 indicates a "poor" sleeper, and a score above 12 is associated with "insomnia."[15] |

*(continued)*

**TABLE AI.** Continued

| Test Name (Abbreviation) | Task Structure | Task Purpose |
|---|---|---|
| Combat Exposure Scale (CES)[c] | A 7-item self-report measure that assesses wartime stressors experienced by service members. The total CES score (ranging from 0 to 41) is calculated by using a sum of weighted scores, which can be classified into 1 of 5 categories of combat exposure ranging from "light" to "heavy." | This scale rates cumulative combat exposure and is highly predictive of PTSD, pain and injury, TBI, depression, and other behavioral sequellae.[16] |
| PTSD Checklist—Military Version (PCL-M)[c] | A 17-item scale assessing symptoms in response to stressful military experiences. This scale assesses PTSD, with subscales including re-experiencing, avoidance/numbing, and hyperarousal. | Higher scores indicate increased PTSD symptomatology. In a military population, scores >49 are likely to have PTSD. For greatest specifically, scores >44 with 3 re-experiencing, 1 avoidance/numbing, and 2 Hyperarousal endorsed as at least "most of the time" are more specific for PTSD and correlate very highly (0.92) with the Clinician Administered PTSD Scale (CAPS).[17] |
| Deployment Stress Inventory (DSI)[c] | Based upon the neurobehavioral symptom inventory with additional items added to assess anger, pain, and sleepiness. Test is a 28-item experimental scale that factors into three domains (cognitive-emotional, somatic, and anger) and five subscales (cognitive, emotional, pain, sleep, and anger). | This experimental measure is intended to be used as a broad psychological screening tool sensitive to combat-related distress, especially reporting of persistent postconcussive symptoms.[18] |

[a]DANA Rapid Battery. [b]DANA Brief Battery. [c]DANA Standard Battery.

sample of nonimpaired service members. The CES correlated mildly with the PCL-m and DSI ($p < 0.01$).

## DISCUSSION

The data presented here represent a first empirical examination of the DANA tool, a portable NCAT that includes both cognitive and psychological tests. Feasibility, reliability, and internal validity were assessed through the administration of DANA to 224 active duty service members (officers and enlisted) from the U.S. Air Force, Navy, and Marine Corps across five extreme environments.

As can be seen in Table II, scores were stable across administrations. Split-half reliability correlations for DANA subtests are within acceptable ranges, and are comparable to those reported for other similar NCAT subtests.[9] ICC measures across administrations were excellent and generally exceeded those reported in similar NCAT subtests although they were comparable to previously reported aggregate NCAT scores.[10] We are currently developing more sophisticated scoring and statistical approaches to score each subtest as well as to aggregate subtests into composite index scores.

Descriptive analysis of the psychological subtests shows that the sample scored, in general, well below scores indicative of clinical problems. From the range of CES scores, it appears that most of the sample had not been exposed to moderate or greater combat. With regard to mean psychological scores and the relevant scoring for cognitive variables, all psychological variables correlate highly with each other, with the exception of the Insomnia Severity Index (ISI) and Primary Care (PC)-PTSD, which had moderate correlations, likely due to having a low number of items (4 and 7 items,

**TABLE AII.** Test Parameters

| | No. of Response Trials | Stimulus Presentation Time (milliseconds) | Maximum Response Time (milliseconds) | Intertrial Interval (milliseconds) |
|---|---|---|---|---|
| SRT | 40 | 900 | 900 | 600 to 3,000 |
| PRO | 32 | 2,000 | 2,000 | 500 to 1,000 |
| GNG | 30 | 1,500 | 1,500 | 1,000 to 1,750 |
| CDS | 72 | 3,000 | 3,000 | 900 |
| CDD | 72 | 6,000 | 6,000 | 900 |
| SPD | 20 | 5,000 | 5,000 | 500 to 1,000 |
| MSP[a] | 30 | 3,000 | 10,000 | 750 to 1,350 |
| STN | 30 | 5,000 | 5,000 | 900 |

[a]MSP also had a delay between the stimulus and the response grids of 5,000 milliseconds.

respectively). Similarly, most cognitive tests correlated moderately with each other, with the exception of CDD, which did not correlate with the other cognitive measures, likely tapping into a different construct than the other measures. In addition, in this nonclinical population, no cognitive tests correlated with any psychological tests. This is to be expected given that the great majority of scores on the psychological tests were well within the "normal" range, and the cognitive scores were closely grouped. Finally, CES did not correlate with any measure in this nonclinical population of mostly noncombat deployed service members.

As can be seen in Table III, DANA compares favorably to existing NCATs in terms of median/mean RT (or % accuracy for CDD) and SD. The CVs are also consistent with CVs reported from ANAM data collected in 2006, 2008, and 2012 cohorts. This suggests that differences in absolute values for RT are most likely due to the testing instrument (mouse click versus stylus) rather than anything implicit in the test itself. Taken together, DANA appears to have adequate reliability and test validity in a sample of nonclinical service members across services and environments. DANA is currently being assessed in postdeployment and clinical samples.

The results reported here suggest that the DANA has promise as a next generation NCAT. Benefits of the DANA include that it (a) includes relevant psychological tests as well as standard cognitive tests; (b) is built on a portable OS with more precise timing than previous NCATs; and (c) is a portable handheld device, which is more versatile than a laptop computer. Future studies of DANA are planned to assess DANA's ability to assist frontline providers to more rapidly and accurately evaluate service members to determine the need for higher level evaluation, treatment, or readiness to return to duty.

## APPENDIX

Table AI describes the eight cognitive tests and seven psychological questionnaires that were selected for the DANA test batteries. Each individual subtest parameters are shown in Table AII including stimulus presentation duration, response interval, and interstimulus interval.

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# Defense Automated Neurobehavioral Assessment (DANA)—Psychometric Properties of a New Field-Deployable Neurocognitive Assessment Tool

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**ABSTRACT** The Defense Automated Neurobehavioral Assessment (DANA) is a new neurocognitive assessment tool that includes a library of standardized cognitive and psychological assessments, with three versions that range from a brief 5-minute screen to a 45-minute complete assessment. DANA is written using the Android open-source operating system and is suitable for multiple mobile platforms. This article presents testing of DANA by 224 active duty U.S. service members in five operationally relevant environments (desert, jungle, mountain, arctic, and shipboard). DANA was found to be a reliable instrument and compared favorably to other computer-based neurocognitive assessments. Implications for using DANA in far-forward military settings are discussed.

## INTRODUCTION

In January 2009, the U.S. Navy Bureau of Medicine and Surgery identified a need to enhance existing battlefield concussion assessment and requested the development of a durable, portable, and field-hardened neurocognitive assessment tool (NCAT) to provide a practical means to conduct neurocognitive and psychological assessment in field deployment settings. The purpose of combining neurocognitive and psychological assessment was to permit more comprehensive evaluation of the broad range of problems that may be encountered during combat deployment. This article describes the resulting NCAT, Defense Automated Neurobehavioral Assessment (DANA); DANA's psychometric properties based on assessment of 224 active duty U.S. service members under challenging field conditions; and presents comparisons to published NCAT data.

DANA consists of three test batteries of different durations and compositions designed for increasingly detailed assessment (Table I). The three batteries include (1) DANA Rapid, a 5-minute battery of three basic reaction-time measures; (2) DANA Brief, a 15-minute test that includes DANA Rapid plus additional neurocognitive tests as well as psychological screening tools for post-traumatic stress disorder (PTSD), depression, and insomnia; and (3) DANA Standard, a 45-minute more comprehensive battery of neurocognitive and psychological tests. This hierarchical set of batteries is designed to facilitate health care providers' access to standardized, reliable, and valid objective and subjective measures. DANA's portability, multiple test batteries, and user-friendly interface enable its use by a wide range of health care providers, from frontline medics/corpsmen to licensed health care professionals.

Establishing reliability and feasibility of this platform in a military population is necessary before attempting clinical validation and utilization. The eventual goal of DANA is to assist clinicians to (a) make rapid and accurate assessment of cognitive and psychological dysfunction secondary to brain injury and/or the psychological wounds and stressors of war,

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**TABLE I.** DANA Test Batteries*

| DANA Rapid (5 Minutes) | DANA Brief (15 Minutes) | DANA Standard (45 Minutes)** |
|---|---|---|
| Simple Reaction Time (SRT) | SRT | SRT |
| Procedural Reaction Time (PRO) | Code Substitution Simultaneous (CDS) | CDS |
| Go/No-Go (GNG) | PRO | PRO |
| | Spatial Discrimination (SPD) | SPD |
| | GNG | GNG |
| | Code Substitution Delayed (CDD) | CDD |
| | SRT | Matching to Sample (MSP) |
| | Patient Health Questionnaire (PHQ) | Sternberg Memory Search (STN) |
| | Primary Care PTSD Screen (PC-PTSD) | SRT |
| | Insomnia Screening Index (ISI) | Combat Exposure Scale (CES) |
| | | PHQ |
| | | Pittsburgh Sleep Quality Index (PSQI) |
| | | PTSD Checklist—Military Version (PCL-M) |
| | | Deployment Stress Inventory (DSI) |

*For detailed test descriptions, see Table AI. **MSP and STN were still under development at the time of this testing and so are not included in the results.

(b) facilitate referral to treatment for wounded service members, (c) monitor recovery, and (d) aid in return-to-duty determination. Thus, DANA is intended to enhance military capability and better ensure a healthy fighting force.

## METHODS

### *DANA Platform*

DANA is a Java-based mobile application that runs on an Android operating system. The primary advantages of Android are that it is open source, open license (Apache 2.0), well supported and based on a Linux kernel, which is nearly ubiquitous. Java has the advantage of being a high-level, class-based, object-oriented language designed as a "write once, run anywhere" solution and thus is portable across a wide range of devices and desktops. DANA, therefore, can run on any Android mobile device and can be used with a stylus or touch screen.

Based on the Navy Bureau of Medicine and Surgery, requirements for MIL-SPEC commercial-off-the-shelf hardware, we conducted a comprehensive trade study and selected the Trimble Nomad, the military-grade-hardened handheld computer used in the current study. A Tektronix 100 MHz analog to digital (ADC) oscilloscope was used to test the input variability of device hardware and device software that could contribute to the overall response times. A push action switch was connected to the ADC, which was then used as the input stylus on the Nomad to measure RT. The interval between two inputs as recorded by DANA and by the ADC was compared over 10 trials. The average difference was 6.8 milliseconds with a standard deviation (SD) of 3.7 milliseconds. By comparison, the input variability with a Microsoft windows personal computer can range from 4–25 milliseconds.[1,2]

### *DANA Test Battery*

Selection of the neurocognitive and psychological tests included in DANA was established by a tri-service, Veterans Administration, and civilian scientific advisory board that included military and civilian neuropsychologists and psychologists, neurologists, and corpsmen. All tests included in DANA's test batteries meet the requirements of the American Psychological Association's standard for tests and measurements and all tests are in the public domain. Eight cognitive tests and seven psychological questionnaires were selected (Table AI) and are divided into three test batteries, as shown in Table I. Tests were selected based upon their potential to address specific deployment-related concerns, such as concussion and combat distress or exhaustion. Although all tests utilized have an extensive literature regarding their reliability and validity, they have not been reported in this specific configuration nor implemented for service members in this manner. The advisory board also contributed to and provided feedback on the user interface design to ensure ease of use by multiple levels of caregivers including the corpsmen, general medical officers, and neuropsychologists.

### *Participants and Procedure*

To evaluate the deployment feasibility of DANA, we recruited 224 active duty service members comprising 40 or more active duty military personnel in each of 5 diverse operational environments. No subjects were excluded, since all service members were fit for duty, not undergoing any disability evaluation, and thus assumed to be healthy. The purpose of assessing service members across diverse environmental conditions was to show the robustness of the hardware and software administration under different operational tempos and to identify any environmental concerns with the reliability of the instrument.

- — Arctic (Thule Air Force Base—Greenland in the winter)
- — Jungle (U.S. Marine Corps Jungle Warfare Training Center—Okinawa, Japan, in the summer)
- — Altitude (U.S. Marine Corps Mountain Warfare Training Center—Bridgeport, CA, approximately 3,000 m)
- — Desert (U.S. Marine Corps Desert Warfare Training Center—Twentynine Palms, CA, in the summer)
- — Shipboard (USS George Washington during high seas in the Western Pacific)

Device performance (e.g., battery life, display characteristics) was evaluated under the specific environmental conditions (e.g., humidity, temperature) through a minimum of 12-hour exposure. The only instrumentation reliability issue was a screen refresh rate delay in the Go/No-Go (GNG) test in the arctic environment. Because this screen rendering delay would affect test results, the rendering process software was redesigned, which successfully mitigated the delay.

The research protocol was approved by the AnthroTronix Institutional Review Board, the VA Institutional Review Board, and received a Department of the Navy Human Research Protections Program review. A letter was obtained from the commanding officer of each test facility and all subjects signed an informed consent document to participate in testing. On Day 1, each subject was tested on all three batteries, the DANA Rapid, Brief, and Standard. Subjects returned on Day 2 to repeat the sequence of batteries resulting in the following protocol:

— Day 1 (approximately 120 minutes)—Consent Process, DANA Rapid, DANA Brief, DANA Standard
— Day 2 (approximately 40 minutes)—DANA Rapid, DANA Brief, DANA Standard (cognitive tests only)

(The above times include 5-minute breaks between each battery.)

A research team of clinical psychologists and technical staff administered testing. Participants were instructed to hold the stylus about 1-cm above the screen, and to respond as rapidly and accurately as possible. All other instructions were embedded within the tests. To minimize learning and practice effects, test stimuli are generated at random and each test has practice trials before the actual test trials. Parameters of the final version of DANA's individual subtests are described in Table AII including each subtest's stimulus presentation duration, response interval, and interstimulus interval.

Data were analyzed in SPSSv20 for descriptive statistics, split-half reliability, test–retest reliability, and cross-test correlations. For internal consistency, we examined split-half correlations of the first and second half set of trials for the first administration of each test on each day. To evaluate test–retest reliability across administrations, we calculated intraclass correlation coefficients (ICCs)[3] that have been used to evaluate reliability for other health status instruments.[4] Because of multiple analyses, significance levels were set to between $p < 0.01$ and $p < 0.001$, depending upon the number

**TABLE II.** Descriptive Statistics for all DANA Variables for Each Administration

| | Task | Administration | *n* | Median RT Correct ± SD | | Average of Median Throughput ± SD | | Percentage Correct ± SD | |
|---|---|---|---|---|---|---|---|---|---|
| 1 | SRT | 1 | 223 | 309.7 | ±65.3 | 199.6 | ±33.4 | 99.7 | ±3.3 |
| | | 2 | 223 | 309.3 | ±64.6 | 199.8 | ±34.6 | 99.5 | ±2.6 |
| | | 3 | 220 | 300.6 | ±55.5 | 204.4 | ±33.8 | 99.4 | ±3.4 |
| | | 4 | 213 | 302.0 | ±53.3 | 202.2 | ±33.4 | 99.3 | ±4.0 |
| | | 5 | 212 | 308.3 | ±65.1 | 200.6 | ±36.7 | 99.3 | ±4.7 |
| | | 6 | 172 | 298.4 | ±68.5 | 207.1 | ±31.7 | 99.7 | ±2.4 |
| | | 7 | 172 | 307.8 | ±77.0 | 202.1 | ±35.7 | 99.4 | ±2.3 |
| | | 8 | 164 | 305.1 | ±49.2 | 200.7 | ±30.6 | 99.6 | ±2.2 |
| | | 9 | 122 | 317.9 | ±69.0 | 195.7 | ±37.5 | 99.7 | ±1.5 |
| | | 10 | 121 | 310.7 | ±54.9 | 197.8 | ±30.7 | 99.8 | ±0.8 |
| 2 | PRO | 1 | 224 | 604.5 | ±101.6 | 100.1 | ±15.5 | 98.3 | ±4.3 |
| | | 2 | 220 | 579.6 | ±91.4 | 103.8 | ±15.1 | 98.1 | ±4.0 |
| | | 3 | 213 | 571.8 | ±84.8 | 104.8 | ±14.2 | 98.0 | ±4.0 |
| | | 4 | 174 | 579.1 | ±79.9 | 103.6 | ±13.4 | 98.3 | ±3.1 |
| | | 5 | 164 | 579.7 | ±95.4 | 104.1 | ±15.6 | 98.2 | ±3.5 |
| | | 6 | 122 | 565.0 | ±84.1 | 105.7 | ±15.0 | 97.6 | ±5.3 |
| 3 | GNG | 1 | 214 | 535.4 | ±96.8 | 114.2 | ±18.5 | 99.1 | ±2.5 |
| | | 2 | 214 | 519.3 | ±86.8 | 117.6 | ±18.5 | 99.3 | ±2.3 |
| | | 3 | 193 | 520.0 | ±91.4 | 116.7 | ±19.9 | 98.2 | ±4.5 |
| | | 4 | 163 | 527.2 | ±97.4 | 116.1 | ±19.2 | 99.0 | ±2.8 |
| | | 5 | 99 | 506.4 | ±98.3 | 120.9 | ±20.8 | 98.8 | ±3.6 |
| | | 6 | 75 | 521.0 | ±109.6 | 117.7 | ±21.7 | 98.4 | ±5.2 |
| 4 | SPD | 1 | 221 | 1690.2 | ±376.3 | 34.4 | ±7.1 | 92.8 | ±5.4 |
| | | 2 | 209 | 1533.0 | ±361.5 | 37.3 | ±9.4 | 90.6 | ±5.7 |
| | | 3 | 172 | 1562.3 | ±383.9 | 37.8 | ±9.6 | 93.1 | ±5.8 |
| | | 4 | 119 | 1456.6 | ±311.4 | 38.2 | ±7.4 | 89.3 | ±6.2 |
| 5 | CDS | 1 | 223 | 1284.9 | ±277.7 | 47.5 | ±9.5 | 97.5 | ±3.1 |
| | | 2 | 212 | 1256.7 | ±234.5 | 47.8 | ±8.9 | 96.8 | ±4.0 |
| | | 3 | 171 | 1228.7 | ±257.0 | 49.8 | ±10.8 | 97.7 | ±3.1 |
| | | 4 | 120 | 1193.4 | ±211.1 | 50.5 | ±9.4 | 97.3 | ±3.2 |
| 6 | CDD | 1 | 212 | 1046.7 | ±221.5 | 55.0 | ±11.9 | 92.1 | ±8.2 |
| | | 2 | 190 | 1004.3 | ±183.1 | 56.2 | ±11.7 | 91.1 | ±9.1 |
| | | 3 | 161 | 996.7 | ±184.2 | 56.8 | ±12.8 | 90.9 | ±9.5 |
| | | 4 | 103 | 956.9 | ±157.4 | 59.6 | ±11.5 | 92.5 | ±7.9 |

**TABLE III.** Comparison to Previously Reported Data[a]

| | | DANA | ANAM (2006) | ANAM (2008) | ANAM (2012) |
|---|---|---|---|---|---|
| SRT | *n* | 223 | 2,261 | 5,237 | 107,413 |
| | Mean[a] | 309.7 | 261.3 | 267 | 261 |
| | SD | 65.3 | 56.1 | 74 | 47 |
| | Ratio | 21.08% | 21.47% | 27.72% | 18.01% |
| PRO | *n* | 224 | — | — | 107,353 |
| | Mean[a] | 604.5 | — | — | 592 |
| | SD | 101.6 | — | — | 90 |
| | Ratio | 16.81% | — | — | 15.20% |
| CDS | *n* | 223 | 2,331 | 5,237 | 107,546 |
| | Mean[a] | 1284.9 | 1,191 | 1,096 | 1,162 |
| | SD | 277.7 | 248.7 | 265 | 272 |
| | Ratio | 21.61% | 20.88% | 24.18% | 23.41% |
| CDD | *n* | 212 | 1,891 | 5,202 | 107,523 |
| | % Accuracy | 92.1 | 88.7 | 86.30 | 90 |
| | SD | 8.2 | 9.3 | 15.80 | 11.4 |
| | Ratio | 8.90% | 10.48% | 18.31% | 12.67% |

[a]Medians are shown for DANA.

of analyses conducted to correct for type-1 error. Psychological measures were scored using conventional methods.

## RESULTS

DANA performed well in all five field environments with no significant difference across data sets; therefore, the data for all five operational environments were combined. The number of total subjects for each test ranged from $n = 75$ to $n = 224$ depending on whether or not the service member was available to participate in all administrations across 2 days. All but one test (Code Substitution Delayed [CDD]) had over 200 subjects for at least two test administrations.

Scores on psychological measures revealed an overall psychologically healthy sample. Combat Exposure Scale (CES) was in the light range (3.7, with 17 indicating moderate exposure). PTSD Checklist—Military Version (PCL-m) (26), Patient Health Questionnaire (PHQ)-8 (4.6), Pittsburgh Sleep Quality Index (PSQI) (5.9), and Deployment Stress Inventory (DSI) (9.7) were each far below the score needed to reach clinical criteria.

Data exclusions included the elimination of trials with anticipatory responses and test administrations indicating random responses (criterion for exclusion was set at less than 65% correct—since tasks are binary, 50% correct represents random responding). No slow RT responses were eliminated, but to mitigate their undue influence we used medians rather than means to describe the data. Less than 1% of the response trials and less than 2% of the test administrations were eliminated based on these criteria. No subjects were eliminated from analysis based upon a criterion of having more than one test administration eliminated in a battery.

Table II shows the descriptive data for each administration of each test, and Table III compares DANA median RT and SD to previously published reports of mean data from the Automated Neuropsychological Assessment Metrics (ANAM, currently used by the U.S. Department of Defense for baseline, predeployment neurocognitive testing) in military personnel.[5–7] DANA uses median correct RT as the relevant metric, whereas ANAM reports means; however, because of the sample size and the normal populations assessed, the mean and median are assumed to be similar for ANAM.

Although not significantly different, absolute RT values may be different because of differing instrumentation (stylus versus mouse button) between ANAM and DANA. It is also possible to use the published ANAM data to calculate Coefficients of Variation (CVs) (ratio of RT to SD of RT) to show stability[8] and these are compared to analogous DANA subtests in Table III.

For reliability within administrations, split-half correlations of the odd–even trials are reported for the first administration of day 1 and day 2 for each test. Correlations were acceptably high ($p < 0.001$) and generally above 0.85—Simple Reaction Time (SRT) (0.91, 0.93), Procedural Reaction Time (PRO) (0.87, 0.86), GNG (0.85, 0.85), Code Substitution Simultaneous (CDS) (0.94, 0.93)—except for Spatial Discrimination (SPD) (0.76, 0.76) and CDD (0.76, 0.82). For test reliability across administrations, the ICC was calculated. The ICC for SRT was 0.95 indicating excellent reliability across the 10 administrations over 2 days. For PRO, GNG, SPD, and CDS, similar reliability was achieved with ICC values of 0.91, 0.95, 0.89, and 0.88, respectively. Only the CDD test did not have high reliability (0.54), which is expected for repeat CDD tests within a short time period because of the change in codes with each administration, resulting in proactive memory interference.

Correlations were also conducted between all psychological and cognitive measures. With the exception of CDD (difficulties using multiple administrations of this subtest because of memory interference were noted above), all cognitive subtests ($p < 0.001$) and psychological tests ($p < 0.001$) were correlated with each other; however, the psychological and cognitive tests did not correlate with each other in this

**TABLE AI.** DANA Test Descriptions

| Test Name (Abbreviation) | Task Structure | Task Purpose |
|---|---|---|
| Simple Reaction Time (SRT)[a–c] | The subject taps on the location of the yellow asterisk symbol as quickly as possible each time it appears. | This task measures pure RT. |
| Procedural Reaction Time (PRO)[a–c] | The screen displays one of four numbers for 3 seconds. The subject presses on a left button ("2" or "3") or right button ("3" or "4") depending upon the number pressed. | A choice RT measure of accuracy, RT, and impulsivity. This choice RT task targets simple executive functioning with easy decision-making capabilities. |
| Go/No-Go (GNG)[a–c] | This is a forced choice RT task relevant to warfighters. A house is presented on the screen with several windows. Either a "friend" (green) or "foe" (white) appears in a window. The respondent must push a "fire" button only when a "foe" appears. | A choice RT measure of sustained attention and impulsivity. The test assesses speed and accuracy of targets, omissions, and commissions. |
| Spatial Discrimination (SPD)[b,c] | Pairs of four-bar histograms are displayed on the screen simultaneously, and the subject is requested to determine whether they are identical. One histogram is always rotated either ±90 degrees with respect to the other histogram. | Assesses visuospatial analytic ability. |
| Code Substitution Simultaneous (CDS)[b,c] | Subjects refer to a code set of 9 symbol-digit pairs that are shown across the upper portion of the screen. A sequence of single symbol-digit pairs is shown below the key, and the subject indicates whether or not the single pair matches the code by pressing Yes or No. | Assesses visual scanning and attention, learning, and immediate recall. |
| Code Substitution Delayed (CDD)[b,c] | After a delay of several intervening tests, the same symbol-digit pairs are presented without the code. The subject indicates whether or not the pairing was included in the code that was presented in the earlier code substitution learning section. | Assesses learning and short-term memory. |
| Sternberg Memory Search (STN)[c] | The subject memorizes a set of five letters, after which letters appear on the screen one at a time, and the subject determines if the letter on the screen is a member of the memory set. | Assesses working memory. |
| Matching to Sample (MSP)[c] | A single 4 × 4 checkerboard pattern is presented on the screen for brief study period. It then disappears for 5 seconds, after which two patterns are presented side-by-side. The subject indicates which of these two patterns matches the first. | A measure of short-term memory, attention, and visuospatial discrimination. |
| Insomnia Screening Index (ISI)[b] | A 5-item scale evaluating perceived insomnia severity and sleep habits. Each item is rated on a 5-point scale (0–4). | The total score ranges from 0 to 28 and higher scores indicate more severe insomnia. A cutoff score of 10 has been shown to indicate insomnia.[11] |
| Primary Care PTSD Screen (PC-PTSD)[b] | Four screening questions designed for use in clinical settings to screen for PTSD, with 3 out of 4 endorsed items suggestive of likely PTSD. | Questions assess hyper-arousal, re-experiencing, and avoidance for PTSD screening. This test is more sensitive than specific, but correlates highly with the PCL.[12,13] |
| Patient Health Questionnaire (PHQ)[b,c] | A 9-item depression scale assessing symptom severity and diagnostic criteria for major depressive disorder. For research purposes, item no. 9 (concerning suicide) was not included, yet research indicates that the scoring, reliability, and clinical validity are almost identical. | A score of 0–9 is likely to have no depression, 10–14 mild depression, 15–19 moderate depression, and 20+ severe depression.[14] |
| Pittsburgh Sleep Quality Index (PSQI)[c] | 19 self-rated items and 5 partner-rated items, which measure sleep quality during the previous month. This scale differentiates "good" from "poor" sleepers based on seven areas: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction over the last month. | This scale is the most widely utilized sensitive and specific self-report measure for insomnia. A score above 6 indicates a "poor" sleeper, and a score above 12 is associated with "insomnia."[15] |

*(continued)*

**TABLE AI.** Continued

| Test Name (Abbreviation) | Task Structure | Task Purpose |
|---|---|---|
| Combat Exposure Scale (CES)[c] | A 7-item self-report measure that assesses wartime stressors experienced by service members. The total CES score (ranging from 0 to 41) is calculated by using a sum of weighted scores, which can be classified into 1 of 5 categories of combat exposure ranging from "light" to "heavy." | This scale rates cumulative combat exposure and is highly predictive of PTSD, pain and injury, TBI, depression, and other behavioral sequellae.[16] |
| PTSD Checklist—Military Version (PCL-M)[c] | A 17-item scale assessing symptoms in response to stressful military experiences. This scale assesses PTSD, with subscales including re-experiencing, avoidance/numbing, and hyperarousal. | Higher scores indicate increased PTSD symptomatology. In a military population, scores >49 are likely to have PTSD. For greatest specifically, scores >44 with 3 re-experiencing, 1 avoidance/numbing, and 2 Hyperarousal endorsed as at least "most of the time" are more specific for PTSD and correlate very highly (0.92) with the Clinician Administered PTSD Scale (CAPS).[17] |
| Deployment Stress Inventory (DSI)[c] | Based upon the neurobehavioral symptom inventory with additional items added to assess anger, pain, and sleepiness. Test is a 28-item experimental scale that factors into three domains (cognitive-emotional, somatic, and anger) and five subscales (cognitive, emotional, pain, sleep, and anger). | This experimental measure is intended to be used as a broad psychological screening tool sensitive to combat-related distress, especially reporting of persistent postconcussive symptoms.[18] |

[a]DANA Rapid Battery. [b]DANA Brief Battery. [c]DANA Standard Battery.

sample of nonimpaired service members. The CES correlated mildly with the PCL-m and DSI ($p < 0.01$).

## DISCUSSION

The data presented here represent a first empirical examination of the DANA tool, a portable NCAT that includes both cognitive and psychological tests. Feasibility, reliability, and internal validity were assessed through the administration of DANA to 224 active duty service members (officers and enlisted) from the U.S. Air Force, Navy, and Marine Corps across five extreme environments.

As can be seen in Table II, scores were stable across administrations. Split-half reliability correlations for DANA subtests are within acceptable ranges, and are comparable to those reported for other similar NCAT subtests.[9] ICC measures across administrations were excellent and generally exceeded those reported in similar NCAT subtests although they were comparable to previously reported aggregate NCAT scores.[10] We are currently developing more sophisticated scoring and statistical approaches to score each subtest as well as to aggregate subtests into composite index scores.

Descriptive analysis of the psychological subtests shows that the sample scored, in general, well below scores indicative of clinical problems. From the range of CES scores, it appears that most of the sample had not been exposed to moderate or greater combat. With regard to mean psychological scores and the relevant scoring for cognitive variables, all psychological variables correlate highly with each other, with the exception of the Insomnia Severity Index (ISI) and Primary Care (PC)-PTSD, which had moderate correlations, likely due to having a low number of items (4 and 7 items,

**TABLE AII.** Test Parameters

| | No. of Response Trials | Stimulus Presentation Time (milliseconds) | Maximum Response Time (milliseconds) | Intertrial Interval (milliseconds) |
|---|---|---|---|---|
| SRT | 40 | 900 | 900 | 600 to 3,000 |
| PRO | 32 | 2,000 | 2,000 | 500 to 1,000 |
| GNG | 30 | 1,500 | 1,500 | 1,000 to 1,750 |
| CDS | 72 | 3,000 | 3,000 | 900 |
| CDD | 72 | 6,000 | 6,000 | 900 |
| SPD | 20 | 5,000 | 5,000 | 500 to 1,000 |
| MSP[a] | 30 | 3,000 | 10,000 | 750 to 1,350 |
| STN | 30 | 5,000 | 5,000 | 900 |

[a]MSP also had a delay between the stimulus and the response grids of 5,000 milliseconds.

respectively). Similarly, most cognitive tests correlated moderately with each other, with the exception of CDD, which did not correlate with the other cognitive measures, likely tapping into a different construct than the other measures. In addition, in this nonclinical population, no cognitive tests correlated with any psychological tests. This is to be expected given that the great majority of scores on the psychological tests were well within the "normal" range, and the cognitive scores were closely grouped. Finally, CES did not correlate with any measure in this nonclinical population of mostly noncombat deployed service members.

As can be seen in Table III, DANA compares favorably to existing NCATs in terms of median/mean RT (or % accuracy for CDD) and SD. The CVs are also consistent with CVs reported from ANAM data collected in 2006, 2008, and 2012 cohorts. This suggests that differences in absolute values for RT are most likely due to the testing instrument (mouse click versus stylus) rather than anything implicit in the test itself. Taken together, DANA appears to have adequate reliability and test validity in a sample of nonclinical service members across services and environments. DANA is currently being assessed in postdeployment and clinical samples.

The results reported here suggest that the DANA has promise as a next generation NCAT. Benefits of the DANA include that it (a) includes relevant psychological tests as well as standard cognitive tests; (b) is built on a portable OS with more precise timing than previous NCATs; and (c) is a portable handheld device, which is more versatile than a laptop computer. Future studies of DANA are planned to assess DANA's ability to assist frontline providers to more rapidly and accurately evaluate service members to determine the need for higher level evaluation, treatment, or readiness to return to duty.

## APPENDIX

Table AI describes the eight cognitive tests and seven psychological questionnaires that were selected for the DANA test batteries. Each individual subtest parameters are shown in Table AII including stimulus presentation duration, response interval, and interstimulus interval.

## ACKNOWLEDGMENTS

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AnthroTronix

# Defense Automated Neurobehavioral Assessment (DANA)

## Science Advisory Briefing
## November 9, 2012

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## Outline

- Background – Original Concept of Operations
- Phase 1: Feasibility Testing
- Phase 2: Reference Data Populations
  - Outcomes: Deployment, Concussion, Psychological Factors
- Ongoing Studies

- Rapid Innovation Fund Proposed SOW
  - Science Objectives
  - Transition Objectives

- Technical Issues (e.g. Timing)

## What is DANA?

The Defense Automated Neurobehavioral Assessment (DANA) is a portable, field-deployable, clinical assessment tool developed for the Department of Defense.



## Purpose

- To assist in the detection of neurocognitive impairment from any cause
  - Concussion
  - Combat-related psychological distress
  - Deployment-related exhaustion
- To help the far forward medic to more accurately detect impairment as soon as possible and if indicated, facilitate triage to higher level of assessment and care
- To assist the General Medical Officer, generalist psychologist, or other allied healthcare professional with supportive diagnostic tools to aid in their diagnosis and disposition, including more accurate return to duty

## Current Solutions Limitations

Limitations of current solutions

- PC and Web based systems have vast timing variability across hardware platforms and operating system versions
- Not mobile/deployable to field environment
- Lack psychological component



## DANA Requirements:

- Development of a state of the art neurobehavioral assessment tool
- Building upon existing NeuroCognitive Assesment Tools (NCAT)
- Adapt for use during deployment
- Include both standardized cognitive and psychological tests
- Embedded tests of effort
- Make it easy to use for all types of providers

## Platform

- Android OS
- Java Implementation
- Stylus or Touch Screen
- Current Devices
  - NOMAD and Galaxy Tablet

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## DANA Test Batteries

| DANA Rapid (5 minutes) | DANA Brief (15 minutes) | DANA Standard (45 minutes) |
|---|---|---|
| Simple Reaction Time | Simple Reaction Time | Simple Reaction Time |
| Procedural Reaction Time | Code Substitution (Learning) | Code Substitution (Learning) |
| Go/No-Go | Procedural Reaction Time | Procedural Reaction Time |
| *Optional*: Combat MACE interview (additional 10 minutes) | Spatial Processing | Spatial Processing |
| | Go/No-Go | Go/No-Go |
| | Code Substitution (Recall) | Code Substitution (Recall) |
| | Simple Reaction Time | Matching to Sample |
| | Patient Health Questionnaire (PHQ-9) | Sternberg Memory Search |
| | Primary Care-PTSD Screen (PC-PTSD) | Simple Reaction Time |
| | Insomnia Severity Index (ISI) | Combat Exposure Scale (CES) |
| | | Patient Health Questionnaire (PHQ-9) |
| | | Pittsburg Sleep Quality Index (PSQI) |
| | | PTSD Check List-Military Version (PCL-m |
| | | Deployment Stress Inventory (DSI) |

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## DANA Rapid

- Beginning with MACE (embedded in DANA)
- Simple Reaction Time
- Procedural (Choice) Reaction Time
- Go/No-Go Reaction Time

  *(about 5 minutes, after the MACE)*



## DANA Brief

Cognitive (~10min)

- Simple Reaction Time
- Code Substitution (digit symbol learning)
- Procedural Reaction Time (choice RT)
- Spatial Rotation (visual rotation)
- Code Substitution Recall (digit symbol recognition)
- Simple Reaction Time

Psychological (~ 6 min)

- PHQ9 (Depression)
- PCPTSD (Traumatic Stress Screen)
- ISI (Insomnia Screening Index)

## DANA Standard

1. Simple Reaction Time
2. Code Sub
5. Procedural Reaction Time
6. Spatial Processing
7. Choice Reaction (Go/No-Go)
8. Code Sub Recall
9. **Match to Sample**
10. **Sternberg Memory Search (letter set)**
11. Simple Reaction Time
12. **CES**
13. PHQ9
14. **PSQI**
15. **PCLM**
16. **DSI – Neurobehavioral Symptom Inventory plus Anger, Pain, Distress**

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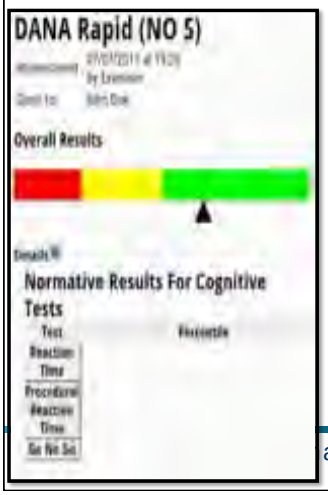
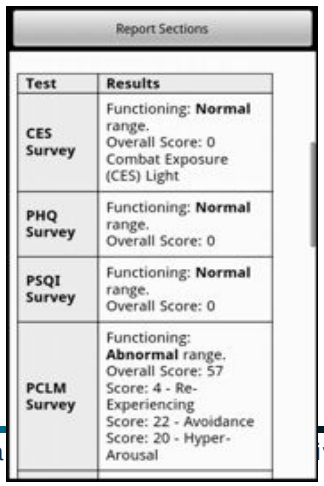
## Output Screens
## – Tailored for use by a range of provider types

Medic MO/BH Neuropsychologist Neurologist




## Phase 1: Feasibility Testing

**Five extreme deployable settings for durability and technical validation** (n=240, >40/site)

- Shipboard (Yokosuka, heavy seas)
- Arctic (Greenland, winter)
- Desert (29 Palms, summer)
- Mountainous (Bridgeport)
- Jungle (Okinawa Humid Summer)



## Outcomes

- **Robustness of technology** – adequate session completion and data collection
- **User experience/interface feedback**
- **Acquired distributions of data for power estimates** for subsequent clinical data collection
  - Total combined population
  - Assessed by environment, age, and gender
- **Reliability Measures**
  - Test-Retest Reliability is adequate (>.64 across all environments)
  - Split-Half, Odd-Even Reliability (.76-.95)
  - Compares favorably to ANAM on similar tests:
    - DANA-ANAM comparison(N=40): DANA had superior test-retest *r*
    - 3 largest ANAM samples published: DANA had similar mean/SD ratios

## Comparison to Published Data

| | | DANA | ANAM (2006) | ANAM (2008) | (ANAM 2012) |
|---|---|---|---|---|---|
| SRT | *n* | 223 | 2,261 | 5,237 | 107,413 |
| | *MD* | 309.7 | 261.3 | 267 | 261 |
| | *SD* | 65.3 | 56.1 | 74 | 47 |
| | *Ratio* | 21.08% | 21.47% | 27.72% | 18.01% |
| PRO | *n* | 224 | - | - | 107,353 |
| | *MD* | 604.5 | - | - | 592 |
| | *SD* | 101.6 | - | - | 90 |
| | *Ratio* | 16.81% | - | - | 15.20% |
| CDS | *n* | 223 | 2,331 | 5,237 | 107,546 |
| | *MD* | 1284.9 | 1191 | 1096 | 1162 |
| | *SD* | 277.7 | 248.7 | 265 | 272 |
| | *Ratio* | 21.61% | 20.88% | 24.18% | 23.41% |
| CDD | *n* | 212 | 1,891 | 5,202 | 107,523 |
| | *PA* | 92.1 | 88.7 | 86.30 | 90 |
| | *SD* | 8.2 | 9.3 | 15.80 | 11.4 |
| | *Ratio* | 8.90% | 10.48% | 18.31% | 12.67% |



## Phase 2: Reference Data Populations

Cross-sectional Comparisons N=646 USMC 1MEF

**Deployment:**

- Never - Prior (>6 mo) - Recent (<6 mo)

**Concussions** (self-report):

- Recency (<6 mo) - Lifetime number

**Cognitive Measures**

- DANA Standard (435)
- DANA Rapid (646)

**Psychological Factors** (meeting criteria for):

- PTSD
- Depression
- Insomnia
- PsychoPhysical Sx
- CES

## Outcomes – Deployment

**Recently deployed** marines scored significantly worse than previously or never deployed on:

- Psychological Factors:
  **CES** (p<.000); **Recent Concussion** (p<.004), **2+ Lifetime Concussions** (p<.005), **Postconcussive Sx** (p<.000),
  **PTSD Sx** (p<.000), **Depression Sx** (p<.02); **Insomnia Sx** (p<.05)
  **Co-morbid complaints** (2 or more of the above, p<.000).

- Cognitive Factors:
  **SRT** (p<.000**)**; **PRT** (p<.001); **GNG** (p<.001)
  NOT on MS, CDS or CDD; and only marginally on SPD.

  Thus, recent deployment was associated with worse psychological symptoms, and worse SIMPLE cognitive tasks, but not more complex cognitive tasks

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## Outcomes - Concussion

**Concussion** was associated with worse psychological scores and some cognitive scores:

- Recent Concussion**:**
  **Post-concussive Sx** (p<.000); **PTSD Sx** (p<.000), **depressive Sx** (p<.000), **SRT** (p<.04), but no other cognitive measures.
  However, this finding was *not upheld when PTSD and Depression were included as covariates* (possibly due to the low cell size).

- Lifetime Concussions:
  Number of lifetime concussions associated with **worse SRT**, and this was *independent of PTSD or Depressive symptoms*.
  **2+ concussions had a 3.6 likelihood of SRT being >20%** above the mean, *independent of PTSD or Depressive Sx (p<.001, OR=3.6).*

  **ROC Curve Analysis** (p<.03) revealed that **3 or more prior concussions predicted SRT>30% above average with a sensitivity of .91 and specificity of .96.**

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## Outcomes – Psychological Factors

*PCL > 50; PHQ > 15; PSQI > 12; DSI > 30; CoMorbid*

**Combat Exposure** per se was NOT associated with worse cognitive functioning. However, CES was associated with worse psychological functioning and concussion which was associated with worse cognitive scores.

**Insomnia** was associated with increased post-concussive, PTSD, and Depressive Sx (p<.000, and accounted for 35-45% of the variance in these outcomes). Insomnia was also associated with worse SRT (p<.000), PRT (p<.024), and CSL (p<.001), again all simple cognitive measures.

**PTSD** (PCL>49), **Depression** (PHQ>14), **and Post-Concussive Sx** (DSI>29) were associated with worse throughput (a measure of speed and accuracy) on *all cognitive tests* (p<.01 - p<.000).

- **PTSD OR=2.9**; **Depression OR=5.4** (4.3 covarying for PTSD) for predicting SRT>20% above average.

**Comorbidity** was associated with reduced performance on *all cognitive measures*.

***DANA cognitive tests appear to be sensitive to psychological factors,*** *at least in a cross-sectional sample.*



## Ongoing Studies

- Mike McCrea – MCW – Head-to Head
- Tom Balkin/Gary Kamimori – WRAIR – Fatigue and Breacher
- Naval and Air Force Academy Sports Teams
- Rob Roach – Univ of Co. – Altitude
- Jim Spira – VA – Psychometrics in clinical populations
- CAPT. Jack Tsao – BUMED – OCONUS MACE vs DANA Rapid
- Mike Russell – DANA Norms – Ft. Hood

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  - Transition Objectives

- Technical Issues (e.g. Timing)



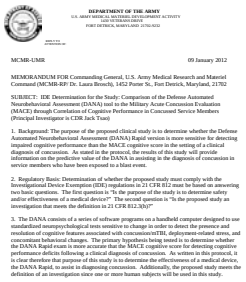
## Rapid Innovation Fund

Transitioning the Defense Automated Neurobehavioral Assessment (DANA) Tool to Operational Use

- Science Objectives
- Transition Objectives
  - FDA
  - Identify Customers

## Why is DANA a medical device?

- Products that are built with or consist of **computer** and/or **software** components are subject to regulation as devices when they meet the definition of a medical device in section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321).
- The relevant text:
  - The term **device** means an **instrument, apparatus, implement or machine** which is intended for **use** in the **diagnosis** of **disease or other conditions** in man or animals.
- Source:
  http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChaptersIandIIShortTitleandDefinitions/ucm086297.htm>



DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL MATERIEL DEVELOPMENT ACTIVITY
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MCMR-UMR 09 January 2012

MEMORANDUM FOR Commanding General, U.S. Army Medical Research and Materiel Command (MCMR-RP/ Dr. Laura Broschi), 1452 Porter St., Fort Detrick, Maryland, 21702

SUBJECT: IDE Determination for the Study: Comparison of the Defense Automated Neurobehavioral Assessment (DANA) tool to the Military Acute Concussion Evaluation (MACE) through Correlation of Cognitive Performance in Concussed Service Members (Principal Investigator is CDR Jack Tsao)

1. Background: The purpose of the proposed clinical study is to determine whether the Defense Automated Neurobehavioral Assessment (DANA) Rapid version is more sensitive for detecting impaired cognitive performance than the MACE cognitive score in the setting of a clinical diagnosis of concussion. As stated in the protocol, the results of this study will provide information on the predictive value of the DANA in assisting in the diagnosis of concussion in service members who have been exposed to a blast event.

2. Regulatory Basis: Determination of whether the proposed study must comply with the Investigational Device Exemption (IDE) regulations in 21 CFR 812 must be based on answering two basic questions. The first question is "Is the purpose of the study is to determine safety and/or effectiveness of a medical device?" The second question is "Is the proposed study an investigation that meets the definition in 21 CFR 812.3(h)?"

3. The DANA consists of a series of software programs on a handheld computer designed to use standardized neuropsychological tests sensitive to change in order to detect the presence and resolution of cognitive features associated with concussion/mTBI, deployment-related stress, and concomitant behavioral changes. The primary hypothesis being tested is to determine whether the DANA Rapid exam is more accurate that the MACE cognitive score for detecting cognitive performance deficits following a clinical diagnosis of concussion. As written in this protocol, it is clear therefore that purpose of this study is to determine the effectiveness of a medical device, the DANA Rapid, to assist in diagnosing concussion. Additionally, the proposed study meets the definition of an investigation since one or more human subjects will be used in this study.



## Two Product Paths (w/in 24 months)

Non-medical device
- Create DANA APP
  - Local device for self-tracking

Medical device
- Finalize FDA Indications of Use
- Science to support those

## Indications for Use

ATinc's device is a portable computerized assessment tool intended for

a. Measuring problem solving speed and accuracy and its change over time

b. Delivery and scoring of standardized psychological questionnaires

ATinc's device is indicated for the general population, able to read and comprehend at 8th grade level and above.



## Windows PC response timing

- Windows version latency component (XP, Vista, 7, 8)
- Hardware configuration latency component
  - System clock
  - Multi-core processor
  - Peripheral manufacturer
- PC build latency component
  - Encryption
  - Virus protection
  - Network clients
- ANAM Response timing*
  - 16.67 msec variability due display refresh
  - 8 msec variability due to USB mouse polling rate
  - 57.4 msec variation across six DoD PC

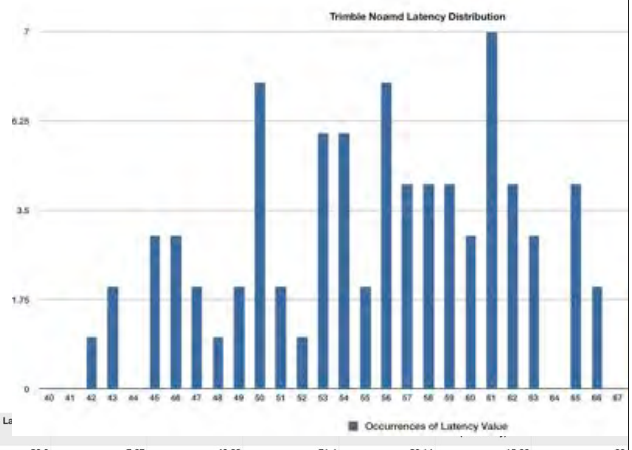
## DANA initial timing test

- Screen light sensor
- Laser reflects off screen
- Laser light sensor
- Oscilloscope




## DANA timing results

- Nomad
  - Range 15msec
  - SD 7msec
- FortisX
  - Range 23ms
  - SD 10msec
- Nexus 7
  - Range 14msec
  - SD 7msec
- Galaxy Tab
  - Range 22msec
  - SD 9msec




| Device | Average Latency | Median La | | | | | |
|---|---|---|---|---|---|---|---|
| Trimble Nomad | 55.1 | 56.0 | 7.27 | 40.88 | 71.4 | 56.14 | 15.26 | 83 |
| Fortis X | 81.14 | 79.56 | 10.17 | 61.36 | 106.96 | 84.16 | 22.8 | 65 |
| Google Nexus 7 | 90.72 | 90.0 | 6.99 | 78.84 | 106.72 | 92.78 | 13.94 | 55 |
| Samsung Galaxy Tab 8.9 | 102.46 | 104.0 | 9.12 | 80.16 | 124.6 | 102.38 | 22.22 | 54 |

Thank You!

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SIMPLE REACTION TIME (SRT)

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## PROCEDURAL REACTION TIME (PRO)


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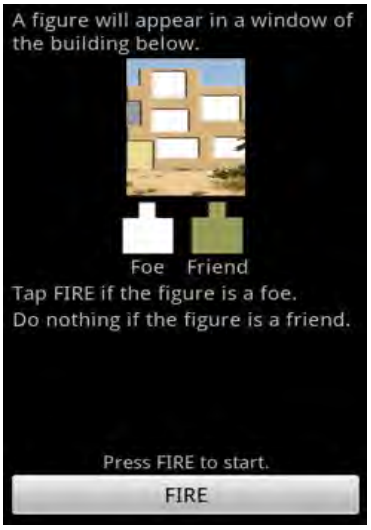
## GO/NO-GO (GNG)





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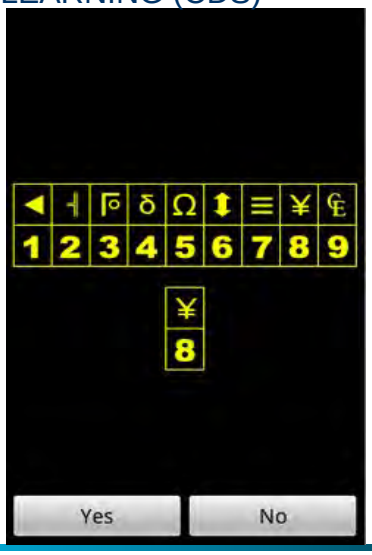
## CODE SUBSTITUTION

LEARNING (CDS)




DELAYED (CDD)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## STERNBERG MEMORY SEARCH (STN)


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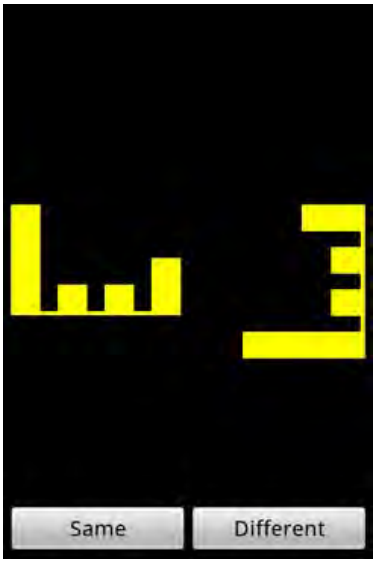
## SPATIAL DISCRIMINATION (SPD)

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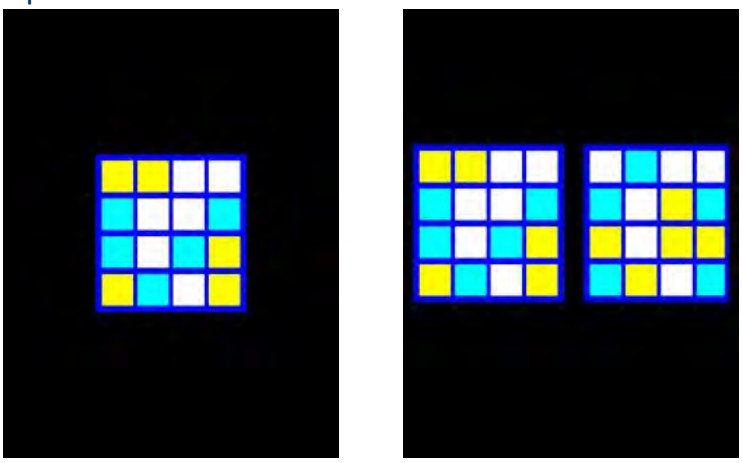
## Match to Sample (MSP)



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Psychological Screening Instrumen
- ISI (Insomnia Screening Index)
- PC-PTSD (4 item screener)

Psychological Clinical Measures:
- PCL-m (PTSD)
- PHQ-8/9 (depression)
- PSQI (insomnia).
- Deployment Stress Inventory (D
  (NBSI + anger/pain/distress)

Combat Exposure Scale (CES)

MACE (assessment of concussion exam)

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# Test-retest reliability of the Defense Automated Neurobehavioral Assessment (DANA) tool as administered to a homogeneous population of healthy collegiate athletes.

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**Abstract**

To enhance concussion assessment, a durable, portable and field-hardened neurocognitive assessment test (NCAT) called the Defense Automated Neurobehavioral Assessment (DANA) tool was recently developed. The DANA provides a practical means to conduct neurological and psychological assessment in the field, and the psychometric properties of the DANA have been previously described. This present work discusses the test-retest reliability of the DANA Rapid test battery, as administered to a homogeneous population of US Air Force Academy football team players ($n_{total} = 342$) before the commencement of the season, during the season, and following the end of the season. We quantify the reliability by way of the standard error of the mean (SEM), and we further describe a consistent methodological approach to discuss reliability in terms of the minimum difference (MD) threshold for the detection of considerable and true change.

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*Keywords:* reliability, cognitive assessment, screening, traumatic brain injury, concussion, sports concussion, NCAT

## 1. Introduction

The Defense Automated Neurobehavioral Assessment (DANA) tool was developed to provide a practical means to conduct neurological and psychological assessment in field-deployable settings. The DANA consists of three test batteries that include neurocognitive assays and psychological screening tools for PTSD, depression, and insomnia. The psychometric properties of the DANA test batteries have been previously described and evaluated and have been found to compare favorably with published data from other NCATs [Lathan et al., 2012]. This present work describes the reliability, or the consistency of a DANA test battery as administered to a homogenous population of US Air Force Academy football team players ($n_{total} = 342$) before the commencement of the team's season, during the season, and following the end of the season.

The efficiency and utility of a neurocognitive assessment tool is determined by its internal consistency, and the measure of test-retest reliability is typically described as the foundation on which a test's validity is established [Cole et al., 2013]. However, a consistent methodology for quantifying reliability is not clearly demonstrated in the current neuropsychology literature: differences in the characteristics of NCAT test batteries, differences in the design of test-retest studies, and insufficiently explained and non-standardized methods of analysis have all served to confound the matter of clearly defining a quantifiable measure of reliability [Weir, 2005; Christie et al., 2010]. It

is important to note that although the reliability coefficient is well-defined (e.g., Baumgartner [1969]; Feldt & McKee [1958]; Streiner & Norman [1995]) the model parameters used to calculate it are application-specific, and thus, any given reliability coefficient is also application-specific and not a universal measure of reliability.

In the field of neuropsychology, the intraclass correlation coefficient (ICC, as delineated by Shrout & Fleiss [1979], and then updated by McGraw & Wong [1996]) is often employed as the stand-alone metric of test-retest reliability, though in other fields (e.g., exercise and sports science, sports medicine, and physical therapy) the reliability (ICC) coefficient is typically reported along with a precision metric provided by the standard error of the mean (SEM) that offers an absolute bound on the measurement of interest [Denegar & Ball, 1993; Learmonth et al., 2013].

By definition, the ICC calculation entails six different possible configuration parameters by which the coefficient is determined, and each model's estimate is unique. A side-by-side comparison of the methods of recent works in neuropsychology (such as Broglio et al. [2007]; Resch et al. [2013]; Cole et al. [2013]) reveals that the methodology of the ICC approach is often not applied in a standardized way, possibly because the ICC model itself is not well-understood. Implicit disagreement between research groups pertaining to which ICC model most accurately describes the test-retest design may stem from confusion around the applicability of ICC methods as developed for inter-rater reliability rather than for test-retest reliability [Weir, 2005]. The two aforementioned types of reliability describe distinctively different situations: inter-rater reliability is the measure of variability amongst the

performance of various subjects (the ratees) as assessed by various judges (the raters), while test-retest reliability measures the variability of within-subject performance, relative to the performance of subjects across the tested population.

The ICC can describe the variability of subject performance relative to the performance of other subjects in the population, but the ICC is inherently biased towards population heterogeneity and demonstrates minuscule sensitivity to within-subject variability [Weir, 2005; Christie et al., 2010]. For example, given the same within-subject, trial-to-trial variability, a larger ICC will be found if the subject population is heterogeneous than if it is homogeneous, and this relative insensitivity to within subject, trial-to-trial variability makes the ICC coefficient less informative of test-retest reliability. Specifically, the stability or instability of a test is most markedly discernible against the backdrop of a homogeneous population, and the within subject variability between test and retest administrations is the pertinent information to be derived from the test-retest design. Furthermore, each ICC model partitions measurement error differently, and choosing the appropriate model parameters for the study design is a nontrivial task.

While attempts have been made to define levels of merit for *reliability coefficients*, generally (most recently in Lezak et al. [2012]), this particular conversation has only recently broadened to include the reliability of automated NCATs. Recent works have found that the reliability coefficients of automated NCATs tend to fall below the merited level of "clinical acceptability" [Broglio et al., 2007; Resch et al., 2013; Cole et al., 2013], and given that the question of which method to employ to quantify reliability has been

raised in the discussion of each of these works, it very well may be the case that such merit is inapplicable for the validation of automated tests. It is also worthwhile to note for the greater context of this discussion that in the literature there is a still pervasive reporting of Pearson's $r$ to assess reliability, even though its use is actively discouraged due the model's inherent disregard for systematic error [Baumgartner, 2000; Bedard et al., 2000; Kroll, 1962; Ludbrook, 2002; Safrit, 1976].

Given the importance of having valid neurocognitive assessment tools, it is necessary to standardize a methodology for quantifying reliability. To ultimately arrive at a definitive method of obtaining test-retest reliability, we take a page from the methods employed by exercise and sports scientists, and in this work we introduce an absolute index for reliable change found from the SEM. The SEM can be calculated in different ways: it can be obtained from the reliability coefficient (this method provides the coefficient's precision), or independently of the reliability coefficient, from the square root of the mean square error. In either case, the SEM carries the same units as the measurement of interest (e.g., throughput or reaction time) and it is informative of within-subject reliability. The minimum difference (MD), or the minimum amount of change in results required to be considered a real effect and not an artifact of associated error, is constructed from the SEM [Weir, 2005]. Following the formalism presented in Weir [2005], we present test-retest reliability measures of a DANA test battery using the reliability coefficient-independent form of the SEM to index the resulting MD. With these measures, we present a generalized, standard methodology for quantifying test-retest reliability.

Table 1: Description of the DANA Rapid test battery.

| Subtest | Task Structure | Task Purpose |
|---|---|---|
| **Simple Reaction Time** (SRT) 40 trials 5 practice trials | Subject taps as quickly as possible on the location of the appearing yellow target. | Reaction time. |
| **Procedural Reaction Time** (PRT) 32 trials 5 practice trials | The screen displays one of four numbers for 3secs, subject presses on a left or right button corresponding to the number. | Choice reaction time measure of accuracy, reaction time & impulsivity. |
| **Go/No Go** (GNG) 30 trials 5 practice trials | Forced choice reaction task relevant to war fighters. Subject distinguishes between appearing "friends" & "foes". | Choice reaction time measure of sustained attention and impulsivity. |

## 2. Methods

### *2.1. The DANA Rapid Tests and Administration*

The DANA Rapid test battery consists of three cognitive tests given in succession, each of which measures reaction time (Table 1 ). On a given testing date, US Air Force cadets participating on the Air Force Academy football team were administered the DANA Rapid along with a demographic survey that were both loaded onto a collection of Trimble Nomads (model 900S). The test administration time totaled $\sim 5$ minutes. Data were collected at the beginning of the season on August 22-24th, 2012, in the middle of the

season on November 6-7th, 2012, and at the end of the season on April 30th-May 1, 2013. If a subject took more than one administration of a test in any given testing session, then only the first administration was included in the following analysis. In addition, a subject must have correctly responded to more than 66% of the test stimuli. Test-retest reliability was calculated from the scores of the first test (or only test) administered per testing date, tabulated for the same subjects across the season.

For each of $n$ subjects we calculated a subject's mean throughput ($< TP >$, with units of $minutes^{-1}$) from correctly answered mean response time data ($< RT_{correct} >$, with units of $milliseconds$),

$$< TP >= \frac{\frac{total_{correct}}{total_{answered}}}{< RT_{correct} >} \times 60,000. \quad (1)$$

The factor of 60,000 converts milliseconds to minutes. We quantify reliability in terms of throughput for the express purpose of garnering performance information that accounts for changes in speed and accuracy. Throughput thus provides a metric for cognitive efficiency by which clinical changes can be assessed more clearly than by changes in reaction time alone.

### *2.2. SEM & MD*

The $SEM$ is an absolute index of reliability and provides insight into the trial-to-trial noise in a given set of data. It carries the same units as the measurement of interest and can be interpreted as the reliability within individual subjects [Weir, 2005; Shrout, 1998]. The $SEM$ can be estimated as the square root of the mean square error ($MS_E$) [Weir, 2005; Eliasziw et al., 1994; Hopkins, 2000; Stratford & Goldsmith, 1997].

The $MS_E$ is related to the sum of squares error, $SS_E$, found from performing an analysis of variation, ANOVA, calculation,

$$MS_E = \frac{SS_E}{(n-1)(k-1)}, \tag{2}$$

where $n$ is the number of subjects and $k$ is the number of test administrations. From the $MS_E$, we can directly calculate the $SEM$:

$$SEM = \sqrt{MS_E}. \tag{3}$$

The $SEM$ is the basis of the minimum difference index, $MD$, or the minimum increment of observable change that warrants consideration as a real change in score and likely not attributable to error:

$$MD = SEM \times z \times \sqrt{2}, \tag{4}$$

where the $\sqrt{2}$ is an artifact of the standard error of the difference of two score results from test and re-test administrations. In Eq. (4), $z$ is the distribution score used to construct the confidence interval. In this work, we report the $MD$ as an absolute index for reliability, constructed in the 95% confidence interval for which $z = 1.96$.

## 3. Results & Discussion

The summary statistics for each testing date are shown (Table 2 ). Only subjects meeting our inclusion criteria for both testing sessions ($T_{1,2}$) were compiled in the analysis. For each subtest, ensemble average throughput performance was similar across testing sessions and higher than that reported

Table 2: Summary statistics for each testing session date (denoted as $T_{1,2}$). Reported mean throughput ($< TP >$) is the mean throughput of $n$ total subjects, and $SD < TP >$ is the associated standard deviation of the mean throughput of $n$ total subjects. The reported $MD$ is calculated with the $< TP >$ from each of $n$ subjects across $T$ administrations, as per Eq.(4).

| $T_{1,2}$ | Subtest | $< TP >$ | | $SD < TP >$ | | $n$ | $MD$ |
|---|---|---|---|---|---|---|---|
| | | $T_1$ | $T_2$ | $T_1$ | $T_2$ | | |
| Aug./Nov. | GNG | 120.2 | 123.8 | 16.91 | 14.96 | 88 | 27.64 |
| | PRT | 102.9 | 106.8 | 13.02 | 12.57 | 89 | 21.86 |
| | SRT | 192.4 | 198.3 | 26.77 | 23.54 | 87 | 38.94 |
| Nov./May | GNG | 123.8 | 127.0 | 14.96 | 16.85 | 40 | 26.65 |
| | PRT | 106.8 | 108.8 | 12.57 | 13.04 | 40 | 18.62 |
| | SRT | 198.3 | 205.3 | 23.54 | 26.19 | 40 | 44.96 |
| Aug./May | GNG | 120.2 | 127.0 | 16.91 | 16.85 | 46 | 27.91 |
| | PRT | 102.9 | 108.8 | 13.02 | 13.04 | 47 | 21.81 |
| | SRT | 192.4 | 205.3 | 26.77 | 26.19 | 47 | 57.55 |

for comparable subtests of other NCATs (see Cole et al. [2013]). The minimum difference in throughput per subtest is similar across testing sessions (Table 2).

For a homogeneous, non-clinical population, the average throughput per subtest is not expected to change across test administrations; in other words, the expectation for test reliability as performed on a healthy and unvaried subject population is that the results of the retest administration should show no statistically significant change from the results of the first test administration. A one-way, repeated measures ANOVA performed on data from each subtest for all of the subjects across testing sessions showed that the $< TP >$ of each group (by test date) is not significantly different from any other ($p > 0.05$) for retest sessions administered in November (from testing in August) and in May (from testing in November). We interpret this result as a demonstration of the test's stability across the time scales of test and retest administrations between August and November, and between November and May.

An increase in throughput between August and May is determined to be statistically significant ($p < 0.05$) for the subtest SRT (see Table 2), but retests in May from August for subtests GNG and PRT showed no significant differences in $< TP >$. As the change only occurred in SRT, this result could be interpreted as a detectable improvement in performance from the beginning to the end of the football season, potentially resulting from the season's duration of practice and good training. Another explanation that has been previously discussed in the literature owes to the possibility of observable practice effects following long ($> 6$ months) testing intervals, and for

younger, cognitively intact individuals, shorter test-retest intervals have been shown to produce better reliability [Dikmen et al., 1999; Roebuck-Spencer et al., 2007]. Considering this phenomenon, the increase in $< TP >$ could be a result of practice effects owing to the duration of the retest interval in May from the initial testing session administered in August.

With the exception of the August-May administration of the subtest SRT, the calculated $MD$ per subtest suggests that an increase or decrease in $< TP >$ of $\sim$20% is indicative of a clinically significant change in cognitive function. Several methods that index a clinically significant change have been previously published (clinically referred to as the Reliable Change index, or RCI, e.g., Jacobson & Truax [1991]; Bruggemans et al. [1997]; Chelune et al. [1993]; Temkin et al. [1999]), and although each of these methods are different in terms of accounting (for practice effects, test variability, and subject demographics among many other clinical parameters), each of these methods distinctly rely on the calculation of a reliability coefficient, arrived at by way of the ICC or by Pearson's $r$. Owing to the aforementioned issues inherent in both of those models, we believe that the $MD$ provides a more informative index of reliability, and we thus report our results utilizing this method in lieu of the traditional RCI.

## 4. Conclusion

The DANA Rapid test battery was administered to cadets of the US Air Force Academy football team before the commencement of the season, during the season and after the season ended. We measured test-retest reliability of the DANA tool and found that the test is stable between test and retest ad-

ministrations. Using the the minimum difference method described in section 2.2, we tabulated an index that describes meaningful change in neurocognitive function based on true changes in test performance, presented in Table 2. From this index we determined that an increase or decrease in $< TP >$ of $\sim$20% will present an indication of a clinically significant change in cognitive function.

## 5. Acknowledgements

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| | | |
|---|---|---|
| Examinee ID: | Date: | Previous Assessments: Yes/No |
| Gender: | Age: | Date of Most Recent Assessment: |

Administrator ID: Device:

| |
|---|
| Description of Traumatic Event:<br><br>Symptoms:<br><br>Changes Since Most Recent Baseline: |

Sleep Score: (Is subject too fatigued to take the test)

**Test Battery: DANA Standard**

| **Cognitive Index** | **Global Score** | **Index Score** | **Rating (Descriptive)** | **Validity (>=66% correct)** |
|---|---|---|---|---|
| Reaction/Executive Capacity (RT) | | | Decline/No Decline/Improvement | Yes/No |
| Visual Memory (VM) | | | | |

| Subtests of Index RT | Test Score | % Rank (comparative) |
|---|---|---|
| SRT | | |
| PRT | | |
| GNG | | |
| SP | | |
| Sternberg | | |

| Subtest of Index VM | Test Score | % Rank (comparative) |
|---|---|---|
| Code Sub Learning | | |
| Code Sub Delayed | | |
| M2S | | |

**Psychological Assessments**

| Test | Test Score | Descriptive Result (Functional/Dysfunctional) |
|---|---|---|
| CES | | |
| PHQ-9 | | |
| PSQI | | |
| PCL-m | | |
| DSI | | |

**Recommendations**

| **This is where you are in the decision making system - Number _____** |
|---|
| |

# DANA Cognitive Test
# Software Verification and Validation

**Testing Objectives:**

1. Verify that all stimuli & responses are being recorded accurately.
2. Verify that responses are being scored correctly.
3. Verify that screen flow is correct for each test (e.g., some survey questions get skipped based on answers to previous questions).
4. Verify that there are no bugs in the overall program.

**Test Cases:** Refer to *DANA Testing Guide* for Coverage

**Testing Procedures:**

| Test Category | Test No. | Test Procedure | Notes |
|---|---|---|---|
| Videotape Testing | 1 | Go through each test, videotaping the device screen as you go; then compare the video to both the report on the device & the exported results data (****comparing labels for both stimuli & responses**). | While taking Cognitive Tests, make sure to try to generate:<br>o Fast trials – faster response time than humanly possible (done by very rapid, repeated taps on the screen over a few trials)<br>o Lapsed trials – letting the stimulus appear and then disappear without a response<br>o Correct trials – entering the correct response<br>o Incorrect trials – entering the incorrect response<br>Export the data via the following options using the DANA Data Manager:<br>o Test Responses<br>o Extended Format<br>Import the exported CSV files into Microsoft Excel to view the data.<br>o For Extended Format, import only the [test name].csv files (ignore the "-survey" or "-stats" appended files) |
| Screen Matching | 2 | Run through all tests and check each screen on the device against the screenshot in the testing guide. | |
| Program Prodding | 3 | Try a variety of things to try to make DANA mess up. | Example A: Pressing the Back button while a report is being generated<br><br>Example B: Repeated quitting and resuming of screenings (pressing the Home button) |

**Testing Checklist:**

Stimuli for all trials are correctly labeled in on-device report.
Responses for all trials are correctly labeled in on-device report.
Stimuli for all trials are correctly labeled in the “Test Responses” export.
Stimuli for all trials are correctly labeled in the “Extended Format” export.
Responses for all trials in “Test Responses” export are correctly labeled.
Responses for all trials in “Extended Format” export are correctly labeled.
All cognitive tests have the same # of practice & actual trials as listed in the Testing Guide.
All screens for all tests match those in the Testing Guide.
No critical bugs found. (critical = compromising full functionality)

## Hazard Mitigation

**See** *DANA Bug Tracking Report* for test results

**DANA Cognitive Test**
**Release criteria**
**Pass/Fail:**

Pass & Fail by classified severity level (1 = Showstopper, 2 = Critical, 3 = Major, 4 = Normal, 5 = Minor

All Cognitive Showstopper (1) bugs have been corrected

All Cognitive Critical (2) bugs have been corrected

All Cognitive Major (3) bugs have been corrected

All Cognitive Normal (4) bugs have been corrected

Most Cognitive Minor bugs (5) have been corrected.
*Minor bugs which remain in the release have been determined to not impact functionality or introduce any hazard. Such bugs are referred to as purely cosmetic defects (e.g., wrong font, color, etc.)*

Signature (project manager): _____

Release Date: _____

Release Version: _____

DANA

Defense Automated Neurobehavioral Assessment

# User Manual


**User Manual for:**

- **DANA v1.5.3**
- **DANA Data Manager v1.1.11**



AnthroTronix

# Acknowledgements:

We wish to acknowledge those who have laid the foundation for the development of DANA, without whose work this would not have been possible. Although DANA is built upon standardized psychological assessment measures and neuropsychological principles, many of the specific applications of these principles and measures have been developed and tested in automated neuropsychological instruments over the past 20 years, including ANAM (Automated Neuropsychological Assessment Metric) and BrainChecker. DANA was not developed to replace these and other automated neuropsychological systems, but rather to extend such approaches to a specific military operational application that was not well served by other existing systems. Therefore, we list those directly involved in the development and testing of DANA, however we will never forget that we are merely building upon the tremendous work of those that preceded us.

**Funding Sources: The US Navy Bureau of Medicine and Surgery (BUMED)**
**The US Army**

**DANA Developed by: AnthroTronix, Inc.**

**Project Personnel:**

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- ***National Center for PTSD:***
  - James Spira, PhD, MPH, ABPP, Research Director
  - Laurel King
- ***National Intrepid Center of Excellence:***
  - Joseph Bleiberg, PhD, ABPP-CN, Senior Scientist
- ***US Navy BUMED:***
  - Jack Tsao, M.D., Contracting Officer of Record

**Collaborating Agencies:**

- The Department of Veterans Affairs, National Center for PTSD
- The US Department of Defense, Department of the Navy, National Intrepid Center of Excellence

# TABLE OF CONTENTS

# Section A – Introduction

The Defense Automated NeuroBehavioral Assessment (DANA) is a clinical assessment tool developed for the Department of Defense for use in the field. The goal of DANA is to create and validate an assessment instrument that will assist first- and second-line providers in the field in determining type of impairment and level of functioning. DANA will assist providers with assessing fitness for duty and triage needs. The tool is intended to aid medical personnel in making an informed disposition in the case where a Service Member may be experiencing difficulty due to brain injury or combat-related physical exhaustion or emotional distress.

DANA can also be used in clinical settings, farther removed from the front lines. Due to a flexible design, the DANA tool can be implemented on a range of mobile devices, depending on the environment.

**DANA VERSION 1.5.3:**
*This version of DANA is designed for establishing reference population datasets that represent a variety of subgroups of service members (e.g., pre-deployed vs. post-deployed, men vs. women). By collecting data with service members across a range of demographics, DANA will be a more applicable neurocognitive assessment tool. In addition, DANA will then be capable of reporting service member performance relative to both individual past performance and cohort (e.g., women) performance.*

DANA is intended to assist at three levels of care:

1) **Front-line Care Providers** in the field (medics, corpsmen) who suspect that the Service Member:
    - Has **recently sustained a head injury**. In this case a 5-minute, rapid, concussion-screening battery can be administered ***(DANA Rapid)*** after the Service Member is safe and stable, and symptoms appear to have diminished (typically 24-48 hours following an incident). Impairment, as measured by poor performance with DANA Rapid, may indicate the need to send the Service Member for a second line assessment. In the case of questionable results, the DANA Rapid can be re-administered within 24 hours to see if function improves.
    - Is **suspected of impaired performance due to any cause, such as a head injury, physical exhaustion**, **distress due to emotional trauma, or other reasons.** In this case, a brief, 20-minute neurobehavioral battery can be administered ***(DANA Brief)***. Impairment, as measured with DANA Brief, may indicate the need to send the Service Member for a second line assessment. In the case of questionable results, the DANA Brief can be re-administered at any time to see if function improves.

2) **Generalist Providers** (General Medical Officers, Clinical Psychologists, and other allied health professionals) at a second-line care facility (e.g., Battalion Aid Station), who desire support in determining:
    - **Specific cause** of the dysfunction (concussion, general combat fatigue, emotional trauma),
    - **Severity of the dysfunction** (degree of impairment in specific areas of cognitive, emotional, and somatic functioning),
    - **Disposition** for what treatment to provide, when to return the Service Member to duty, or if to triage to a higher level of care.

    For these purposes, the full 45-minute battery can be administered ***(DANA Standard)***, providing a summary of functioning in cognitive, emotional, and somatic domains, as well specific results by test. Ideally, the Provider will have access to DANA Rapid or Brief data previously administered in the field by a Front-line Responder.

3) **Specialist Providers** (Neuropsychologists, Neurologists, Psychiatrists) who wish to delve into the details of specific test results in order to obtain more fine-grained information.

DANA is intended to provide support that is most needed at each of these three levels of care, with appropriate tests and reports. Data and corresponding reports can be viewed on the screen, as well as uploaded to a PC in order to support report writing and integration with medical records.

# A-1 DANA Objective

The objective of DANA development and data collection is to create and validate a NeuroBehavioral assessment instrument that will:

1) Assist first responders and second line providers in the field to determine the cause and severity of suspected impairment:
    - Adequately assess if a behavioral problem exists (improved sensitivity).
    - Discriminate between concussion and deployment-related stress (improved specificity).
    - Help determine the severity of the problem.

2) Assist with the determination of fitness for duty vs. the need for a higher level of care.

# A-2 Current DOD Neuropsychological Assessment

The Automated Neuropsychological Assessment Metrics (ANAM) tool is currently used to assess, as of 2012, close to 1 million Service Members prior to deployment.

Some benefits of using the ANAM as an assessment instrument are as follows:

- The ANAM uses standardized neuropsychological tests sensitive to cognitive change;
- The ANAM has established normative reference groups and many research studies which confirm its utility for various uses;
- The ANAM can be rapidly administered and automatically scored; and
- The ANAM has the potential to compare pre and post concussion scores to determine if significant impairment has occurred.

However, the ANAM has some limitations to its use. For example, the ANAM test:

- Lacks specificity in detecting impairments due to any cause;
- Does not distinguish among concussion, deployment exhaustion, and emotional distress;
- Uses CONUS “laboratory” baseline testing which may not adequately capture baseline status during deployment;
- Testing cannot occur close to the time of an incident;
- Is not easily administered and utilized by first line responders as well as advanced medical personnel; and
- May have difficulty determining the validity of the testing session, as well as difficulty interpreting expected change with repeat administrations.

Because of these issues, only about 10,000 personnel have actually been retested post-deployment using ANAM.

# A-3 Purpose of DANA

The DANA tool was developed in an effort to mitigate the limitations associated with ANAM testing.

DANA draws from the best that ANAM and other tools have to offer:

- Using standardized neuropsychological tests sensitive to change;
- Distinguishing among concussion, deployment exhaustion, and emotional distress through incorporating behavioral assessments;
- Allowing for multiple baseline assessments under field deployable conditions by First-Line responders (corpsman / medic), as well as senior medical personnel in order to capture true baseline status during deployment;
- Allowing for testing to occur close to the time of an incident;
- Easily administered and utilized by first line responders as well as advance medical personnel;
- Obtaining post incident testing as needed in the field;
- Determining the validity of the testing session through tests of effort; and
- Interpreting expected change with repeat administrations through establishing a “reliable change index.”

# A-4 DANA System Components

There are six main components that comprise the DANA system. These six components are shown in the figure below.

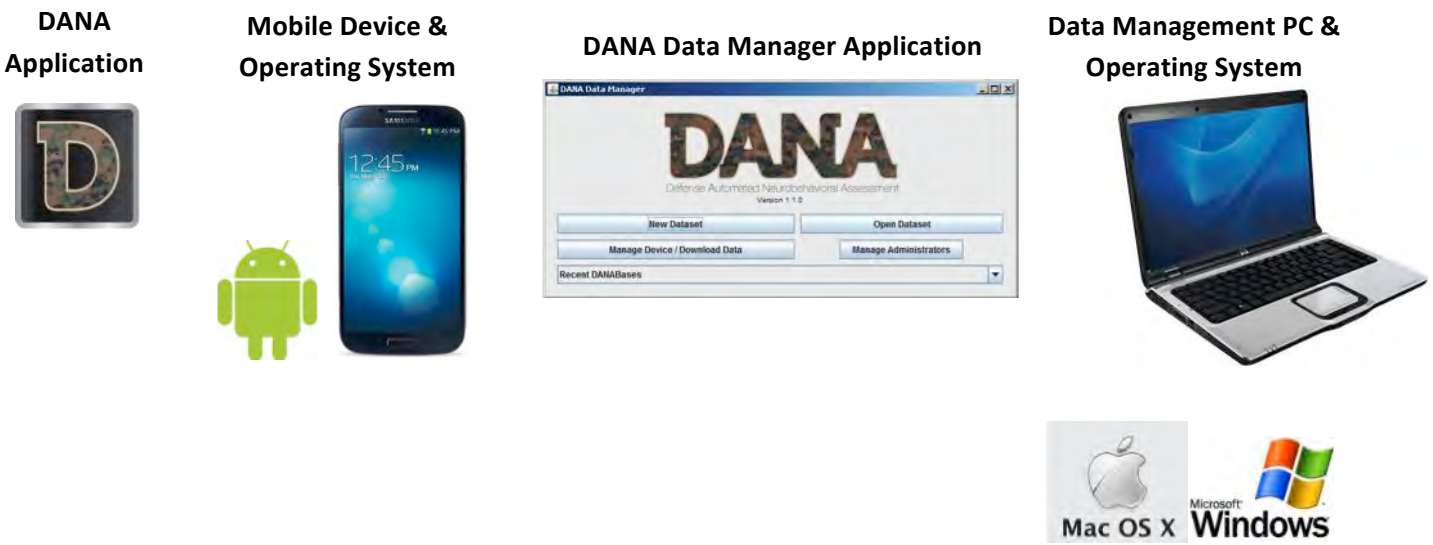



Figure 1

# A-5 Features of DANA

## Environment

- DANA: Android operating system
- DANA Data Manager: Windows, Mac OS

## Compatibility

- Mobile devices with 480x640 (HDPI) displays or screens 7in (diagonal) or larger
- Android versions: Android API Level 7 or higher (Android 2.1 (Eclair) or better)

## Data Encryption

- All data collected by the DANA System are encrypted by the DANA application on the mobile device via 128 to 256-bit AES encryption, depending on the mobile device's capabilities. Data can only be decrypted via the DANA Data Manager by someone with full Administrator rights (via an export option).

## Data Transfer to a PC

- Encrypted data files can be transferred to a PC via wired USB

## Data Backup to a PC

- The DANA Data Manager allows you to perform a complete backup of a mobile device's data to a PC.

## Results

- Report auto-generated (and viewable) post-screenings on mobile device
- Report also viewable on a PC

## Data Export Options

- CSV, PDF, HTML, or XML formats
- Summary or trial-by-trial level data

# A-6 System Requirements

**Mobile Device:**

- Operating System: Android API Level 7 or higher (Android 2.1 (Eclair) or better)
- Display: 480x640 (HDPI) or screens 7in (diagonal) or larger

**Data Management PC:**

- Operating System: Windows XP (service pack 2), Windows 7, or Mac OS X
- RAM: 3GB
- Storage: 200MB free
- Processor: X86 (Intel or AMD), 2GHz
- Ports: 1 USB 1.0 (or better)
- Display: 1024x768
- Java version 6, update 12

Note: DANA v1.5.2 (or prior) will not run properly in Android v4.3 (or later) due to a data encryption incompatibility.

# A-7 General Flow of DANA

DANA has a general overall flow to setting up and starting a screening, which can mostly be described by the figures below. Steps involved in the general use of DANA are outlined below.

Note: This section gives a high-level overview of DANA. Detailed steps for navigating the DANA application are provided in subsequent sections of this user manual.

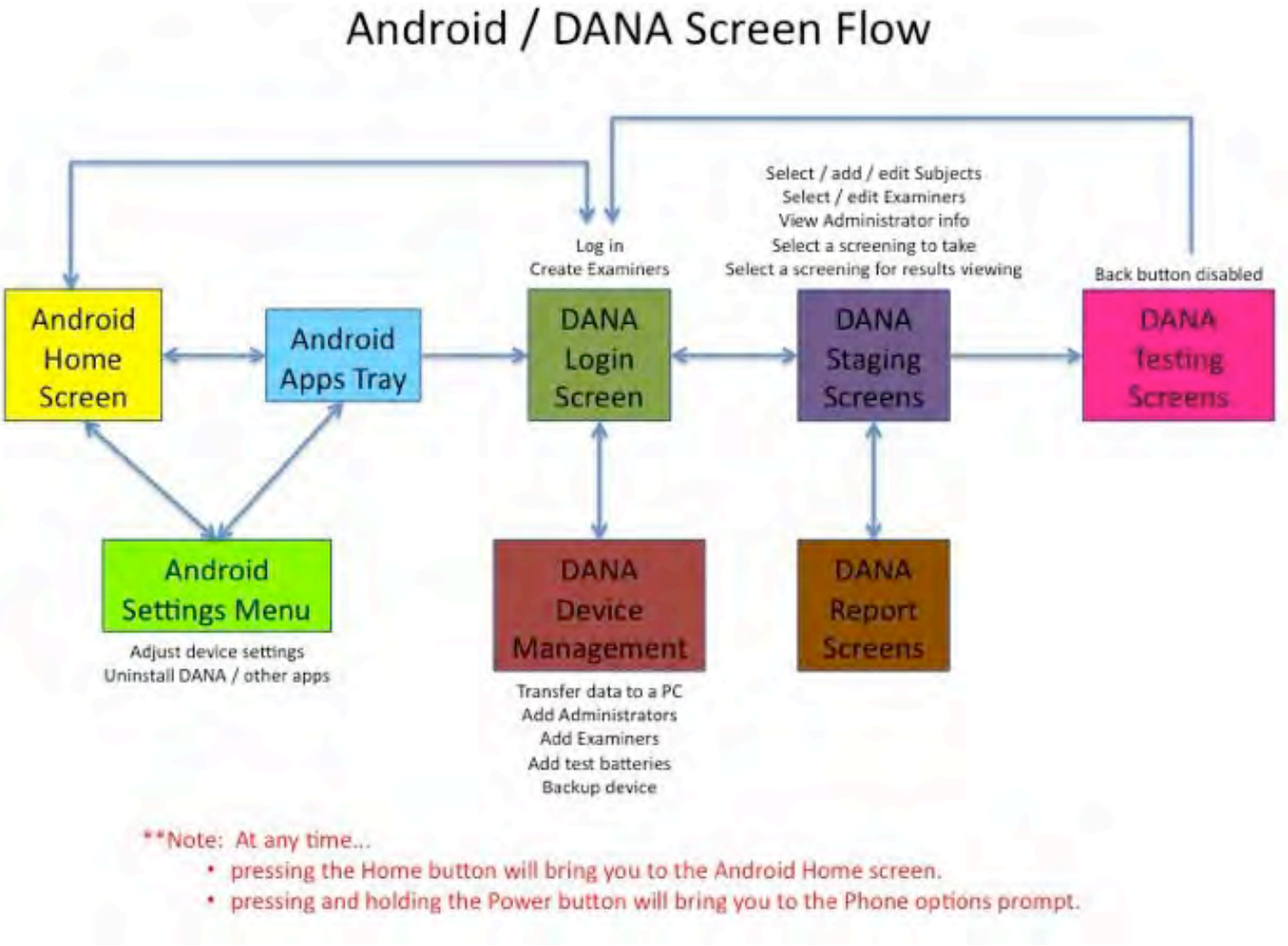



Figure 2

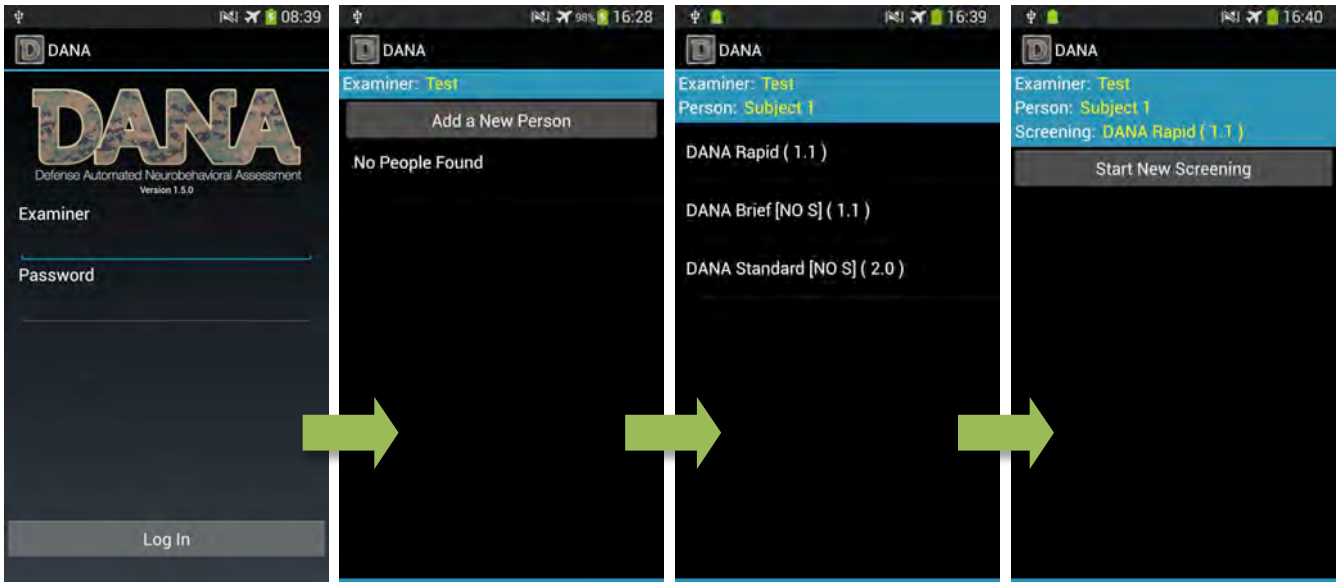
1) Set up an Administrator (complete this step only once).
2) Create an Examiner and log in (**Figure 3a).**
3) Staging (**Figure 3b-3c**).
    a. Select existing / set up new subject.
    b. Select appropriate screening (e.g., DANA Rapid).
4) Start the selected screening (**Figure 3d**).

This basic process will be the same each time an Examiner sets up a screening for a Subject. However, following a completed screening, this basic flow is slightly different, as described below.

For security and privacy reasons, once a screening has begun, the Examiner is effectively logged out of the application. Therefore, when a Subject completes their screening, the Examiner must log in again to continue. After selecting *Screening Completed*, the Examiner can either log in immediately or select *Log In as another*

*Examiner* to get to a fresh Login screen. From there, another Examiner can log in, or you can access the Login screen menu (to transfer data or create a new Examiner).

Once an Examiner is logged in again, they are brought to the Staging screen is shown. From the Staging screen, the Examiner can either view the results of the screening just completed or set up another screening.




a b c d

Figure 3

# Section B – DANA Field Concept of Operations (CONOPS)

DANA is comprised of three primary test batteries:

- DANA Rapid (5-15 min)
- DANA Brief (15 min)
- DANA Standard (45 min)

Each test battery is designed for different purposes and scenarios. The concepts of operations below outline example scenarios for all three batteries.

## CONOPS #1 – DANA Rapid

**Who:** **First Responders (Corpsman / Medic)**
**Where:** **Front Line**
**Why:** **Suspect Concussion**
***Action:*** ***Use DANA Rapid***

This short screening battery should be used when the medical professional has knowledge of a concussion within 48 hours of a reported head trauma. The DANA Rapid assessment takes 5-15 minutes to complete, depending upon whether the 10-minute MACE (Military Acute Concussion Evaluation) is administered. The following steps should be followed in conducting the evaluation and viewing results.

1) Transport the Subject to a secure location.
2) Read the Sample Script to the Subject (*see Sample Script below*).
3) Log into DANA and administer DANA Rapid to the Subject.
4) Log back into DANA and view the screening results.

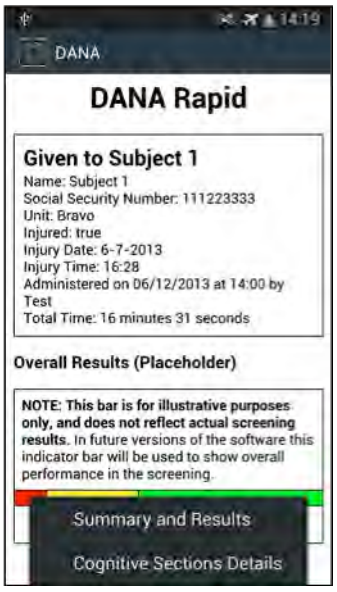



Figure 4

<u>Sample Script for Examiner (prior to administering a test)</u>:
"This toolkit contains measures of how quickly and effectively you can do certain tests. Speed is as important as accuracy. It only takes a light tap on the screen to register a response. In order to get the best results, you should hold the stylus within a quarter inch of the screen, like this..."
<demonstrate>

"Many of the timed tests have a practice section that comes first. If you have any questions, or are unclear about what you are being asked to do, feel free to ask. I will be glad to answer any general questions about these tests when you are done.

Are there any questions about what you will be asked to do over the course of the test?"

Note: Ideally, if the device can be put on a flat surface, even on something like a backpack on the Subject's lap, the process will be easier and more accurate.

- DANA Rapid Only: Hand the mobile device to the Subject and instruct them to read the on-screen instructions and select *Continue* and then *Start Screening* on the screen to begin. Also tell them to bring the mobile device back to you once the screening is completed.
- MACE Only: Keep the mobile device in your possession, select *Continue* and then *Start Screening*, and then begin the MACE interview, entering the Subject's responses on the mobile device.
- Once the screening is completed, the screen will display, "Screening completed. Please return the device to the examiner."

# CONOPS #2 – DANA Brief

**Who:** **First Responders (Corpsman / Medic)**
**Where:** **Front Line**
**Why:** **Suspect Impairment Due to Any Cause**
***Action:*** ***Use DANA Brief***

This short screening test battery is used for suspicion of impairment due to any cause (e.g., concussion, combat fatigue, emotional distress). Administration of the test battery requires approximately 15 – 20 minutes. The following steps should be followed in conducting the evaluation and viewing results.

1) Transport the Subject to a secure location.
2) Read the Sample Script to the Subject (*see Sample Script at the beginning of this section*).
3) Log into DANA and administer DANA Brief to the Subject.
4) Log back into DANA and view the screening results.

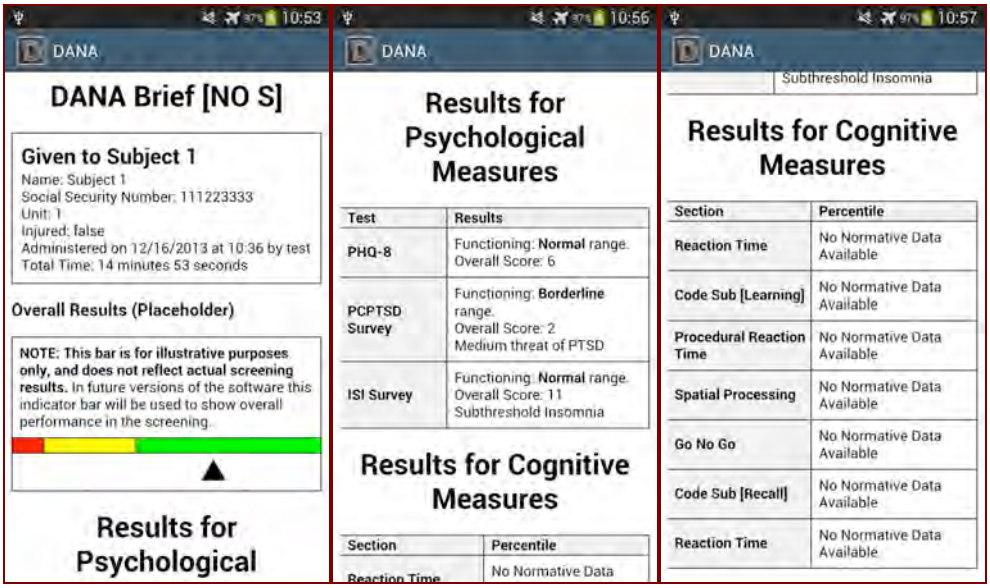



Figure 5

# CONOPS #3 – DANA Standard

**Who:** **Generalist Providers (Psychologist, Psychiatrist, General Medical Officer, Allied Healthcare Professional)**
**Where:** **Second-Line Care**
**Why:** **Suspect Impairment Due to Any Cause**
***Action:*** ***Use DANA Standard***

The Subject may have been referred following concerns supported by DANA Rapid (concussion) or DANA Brief (degraded function due to any cause) screenings. The DANA Standard assessment battery requires approximately 45 minutes, and assesses the Subject's cognitive functioning and behavioral factors indicating combat fatigue or suggesting emotional distress. The DANA Standard battery is intended to assist licensed healthcare providers in their determination of the type of problem, extent of problem, and disposition. The following steps should be followed in conducting the evaluation and viewing results. The details in the report are intended to assist the generalist provider with determining the type and extent of possible impairment.

1) Transport the Subject to a secure location.
2) Read the Sample Script to the Subject (*see Sample Script at the beginning of this section*).
3) Log into DANA and administer DANA Standard to the Subject.
4) Log back into DANA and view the screening results.

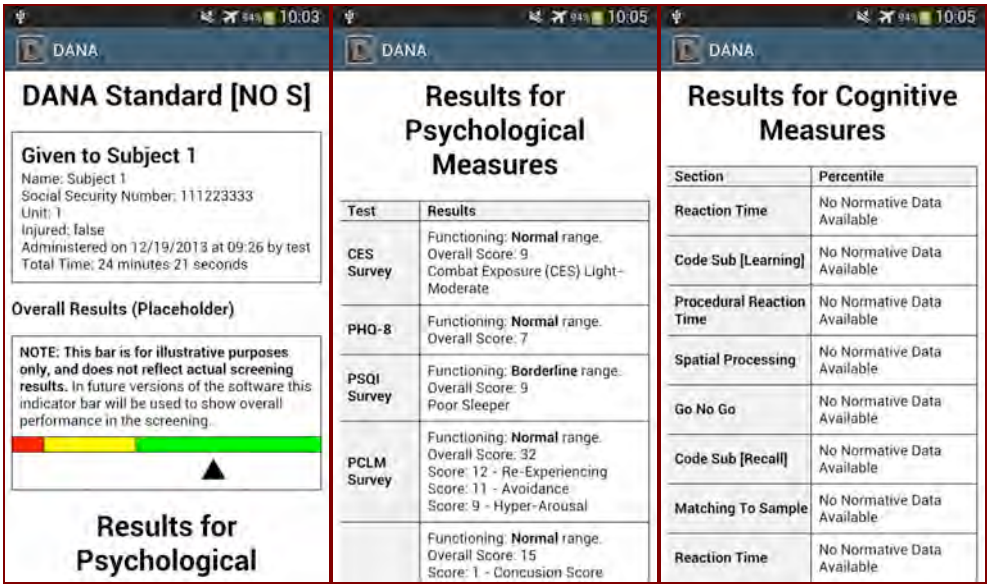



Figure 6

# CONOPS #4 – DANA Standard

**Who:** **Specialist Providers (Neuropsychologist, Neurologist, PTSD Specialist)**
**Where:** **Third-Line Care**
**Why:** **Suspect Impairment Due to Any Cause**
***Action:*** ***Use DANA Standard***

The Subject may have been referred following concerns supported by DANA Rapid (concussion) or DANA Brief (degraded function due to any cause) screenings; or the Subject may have already been administered the DANA Standard. The DANA Standard assessment battery requires approximately 45 minutes and assesses the Subject's cognitive functioning and behavioral factors indicating combat fatigue or suggesting emotional distress. The DANA Standard battery is intended to assist licensed healthcare providers in their determination of the type of problem, extent of problem, and disposition. The following steps should be followed in conducting the evaluation and viewing results. The details in the report are intended to assist the specialist provider with determining the type and extent of possible impairment.

1) Transport the Subject to a secure location.
2) Read the Sample Script to the Subject (*see Sample Script at the beginning of this section*).
3) Log into DANA and administer DANA Standard to the Subject.
4) Log back into DANA and view the screening results.

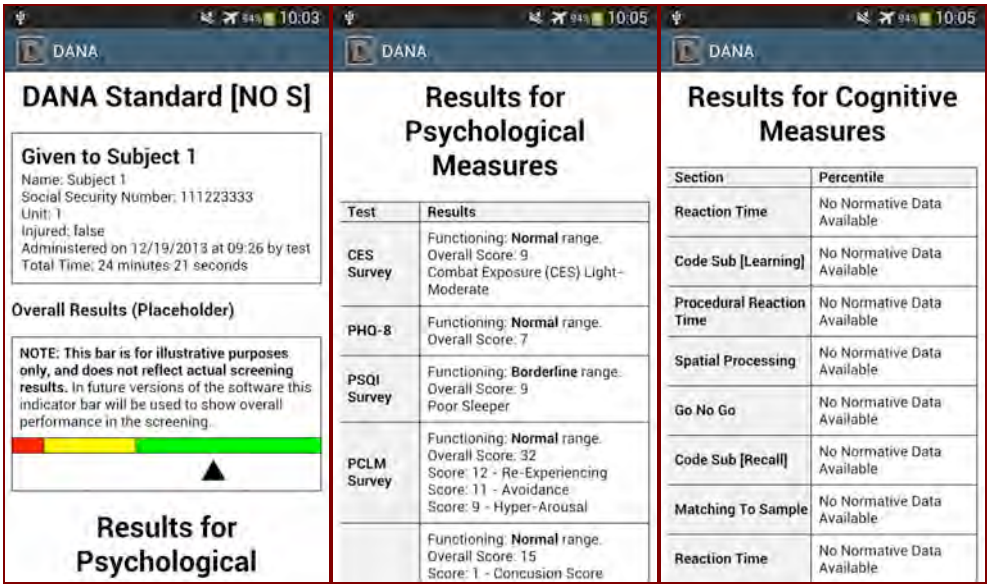



Figure 7

# Section C – Data Management PC Overview & Setup

## C-1 Overview

**What you will need to complete this section:**

- An Internet connection
- Data management PC(s)
- Mobile device(s) and its USB data cable
- Any files provided to you (if any)

**System Requirements (minimum):**

- Operating System: Windows XP (Service Pack 2), Windows 7, or Mac OS X
- RAM: 3GB
- Storage: 200MB free
- Processor: X86 (Intel or AMD), 2GHz
- Ports: 1 USB 1.0 (or better)
- Display: 1024x768
- Java version 6, update 12

The first step in getting started with the DANA system is to set up and configure the data management PC.

The DANA system requires two main components for full functionality: (1) a mobile device and (2) a data management PC. The data management PC must be configured first in order to then configure and use the mobile device.

## C-2 Setup

### Step 1

**Copy any files provided to your data management PC.**

1. Copy any files provided to your data management PC.
2. Unzip any zip files. This should create folders with the same names as the zip files.

# Step 2

## Install the appropriate Microsoft Visual C++ package on the data management PC (Windows XP only).

1. Determine if the version of Windows XP running on your data management PC is 32-bit (x86) or 64-bit (x64):
   - From the Start Menu, select *Run*.
   - Type *msinfo32* and click *OK*.
   - A Window containing your system's information should appear. In that window, look for *System Summary* and look for *System Type*. This should tell you if your system is x64 or x86.
2. Launch the correct file (provided to you):
   - For 32-bit Windows XP (x86): vcredist_x86 (2010).exe
   - For 64-bit Windows XP (x64): vcredist_x64 (2010).exe
3. Complete the installation procedure that follows, accepting all default configurations.

# Step 3

## Install the mobile device driver on the data management PC (if necessary).

Your mobile computer will likely require a specific USB driver to be installed in order to communicate with the PC. A few common scenarios are described below.

Note: Once you install the correct driver on your PC, that PC should automatically use the driver for any other mobile computers of the same type / manufacturer that you plug into the PC.

→ For additional guidance / tips on installing the correct USB driver, see the following website: http://developer.android.com/tools/extras/oem-usb.html

- When you first plug your mobile computer into the data management PC, the driver files may automatically be located and installed by the PC.

- If the first scenario does not apply and no driver files were provided to you, visit the website of the manufacturer of your mobile computer (e.g., Samsung, HTC, Google), search for a USB driver install file, and follow the installation process.
  - For Samsung devices, a generic USB driver install file is located at the following website: http://developer.samsung.com/android/tools-sdks/Samsung-Andorid-USB-Driver-for-Windows

- If the first two scenarios do not apply, but driver files were provided to you AND you have the mobile computer in your possession:
  1. Plug the mobile computer into the data management PC with the USB cable provided.
  2. A Found New Hardware Wizard window should appear (Figure 3) asking about connecting to Windows Update. Select No, not this time and click Next.
  3. The next window in the wizard should ask you what you want the wizard to do (Figure 4). Select Install from a list or specific location (Advanced) and click Next.
  4. The next window in the wizard should ask you to choose your search and installation options (Figure 5). Select Search for the best driver in these locations and then select the checkbox

next to Include this location in the search. Click Browse, then navigate to and select the folder containing the driver files and click OK.

5. The wizard should then install the driver software for you.


Figure 8

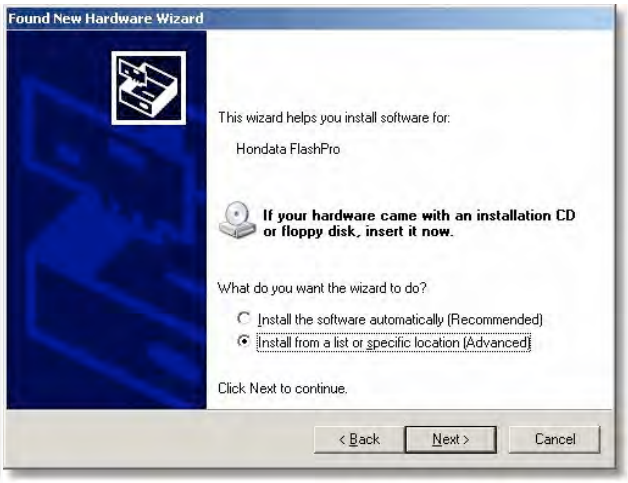



Figure 9


Figure 10

# Step 4

## Install a Java JDK on the data management PC (Windows only).

Install and setup the latest Java JDK (Java Development Kit) for your operating system via one of the following options:

**Option 1:** Download the JDK from:
http://www.oracle.com/technetwork/java/javase/downloads/index.html

**Option 2:** If a JDK file was provided to you, copy that JDK file to the data management PC.

Note 1: Make sure to download and install the x86 (32-bit) version (even if you are using 64-bit Windows).

Note 2: Also make sure to install the full JDK, not a “demo” or “sample” version.

# Step 5

## Install the Java Cryptography Extension (JCE) Unlimited Strength Jurisdiction Policy Files.

1. Go to the website below, accept the license agreement, and download the associated file.
   http://www.oracle.com/technetwork/java/javase/downloads/jce-7-download-432124.html
2. Unzip the file. This should create a new folder with the following files:
   - local_policy.jar
   - README.txt
   - US_export_policy.jar
3. Navigate on your computer to the following directory:
   C:/Program Files/Java
   You should find “jre” and / or “jdk” folders here (see an example in **Figure 11a** below).
   Sort these files by date and open the folder that was most recently modified.
4. Within this folder, open the “lib” folder, and then open the “security” folder (see **Figure 11b** below).
5. Copy the two .jar files listed above in to this “security” folder. If prompted, select the “Move and Replace” option.

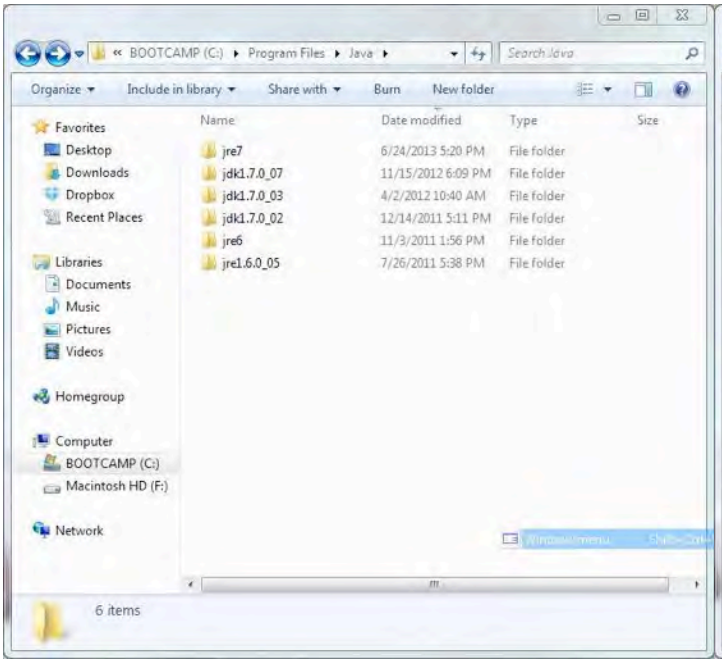



Figure 11a

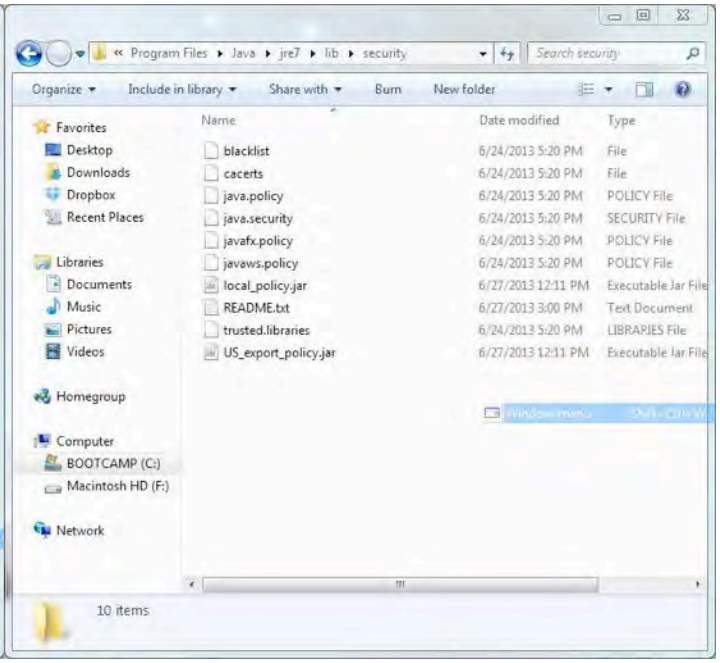



Figure 11b

# Step 6

## Install the Android SDK on the data management PC.

Note: You will need an Internet connection to complete this step. (Only Google may distribute the Android SDK or its components, per the SDK license.)

1. Go to the following website: http://developer.android.com/sdk/index.html
2. Click *DOWNLOAD FOR OTHER PLATFORMS* (at the bottom of the page).
3. In the *SDK Tools Only* section of the tables that appear (see **Figure 12** below), select the Windows installer option, confirm that you agree to the use terms, and click the download link. The SDK installer should begin downloading.
4. If the installer does not automatically launch, locate the installer file you downloaded and launch it.
5. Complete the install process.

Note: Make sure to install the SDK in a familiar location (e.g., Desktop or My Documents). You will have to locate these files later. **DO NOT SAVE THE SDK TO YOUR C:\Program Files DIRECTORY.** (If the SDK is saved to the Program Files directory, the files may get permanently deleted if you uninstall the DANA Data Manager in the future.)

**ADT Bundle**

| Platform | Package | Size | MD5 Checksum |
|---|---|---|---|
| Windows 32-bit | adt-bundle-windows-x86-20130522.zip | 446736316 bytes | 53345fa4121fa58cc048f66c3af3bae9 |
| Windows 64-bit | adt-bundle-windows-x86_64-20130522.zip | 446864400 bytes | b28817f62e7f54e3c683841b61b65564 |
| Mac OS X 64-bit | adt-bundle-mac-x86_64-20130522.zip | 409047751 bytes | 3f4d05206d66e402e87b27a6b3dcf0f9 |
| Linux 32-bit | adt-bundle-linux-x86-20130522.zip | 439988972 bytes | 1fdd8d7537ab9217d61d32ab912f0243 |
| Linux 64-bit | adt-bundle-linux-x86_64-20130522.zip | 440275051 bytes | e38751ff372a8d6208fcef5659133e98 |

**SDK Tools Only**

| Platform | Package | Size | MD5 Checksum |
|---|---|---|---|
| Windows 32 & 64-bit | android-sdk_r22.0.1-windows.zip | 113483496 bytes | cb7f7703450afa5914fb4b8b8332a9f3 |
| | installer_r22.0.1-windows.exe (Recommended) | 93479015 bytes | 81621d3b164f81f91e066011b325f88f |
| Mac OS X 32 & 64-bit | android-sdk_r22.0.1-macosx.zip | 77206237 bytes | 5c20497d7f7b9d28ee30e57cbf769c8c |
| Linux 32 & 64-bit | android-sdk_r22.0.1-linux.tgz | 105617062 bytes | 56ed27d456b4f0e0d3090b24f9b06757 |

Figure 12

## Step 7

**Install the Android SDK Platform Tools on the data management PC.**

Note: You will need an Internet connection to complete this step (due to Android SDK distribution limitations).

1. Start the Android SDK Manager either as the last step of the installer, or via the Start menu. When the Android SDK Manager starts, available items (packages) for install will be shown in the left column (see **Figure 13**).
2. Some of these items may already be selected (automatically); if this is the case, deselect all of these items.
3. Then select (i) *Android SDK Platform-tools*, (ii) *Android SDK Tools*, and (iii) *Android SDK Build-tools* (in the Tools folder) and (iv) *Google USB Driver* (in the Extras folder) and click *Install 4 packages...* (bottom right of window).

   Note: *Android SDK Tools* may already be installed.
4. A new window will appear; select *Accept All* and then click *Install*.
5. The subsequent package install process will then proceed. When the install process has completed, the Android SDK Manager Log window will likely display *Done loading packages* at the bottom.

If you are asked if you want to restart the ADB after the install process is completed, choose *Yes*.

In Mac OS: Start the Android SDK Manager by launching the "android" executable in the "tools" folder, which is in the folder containing the SDK files.

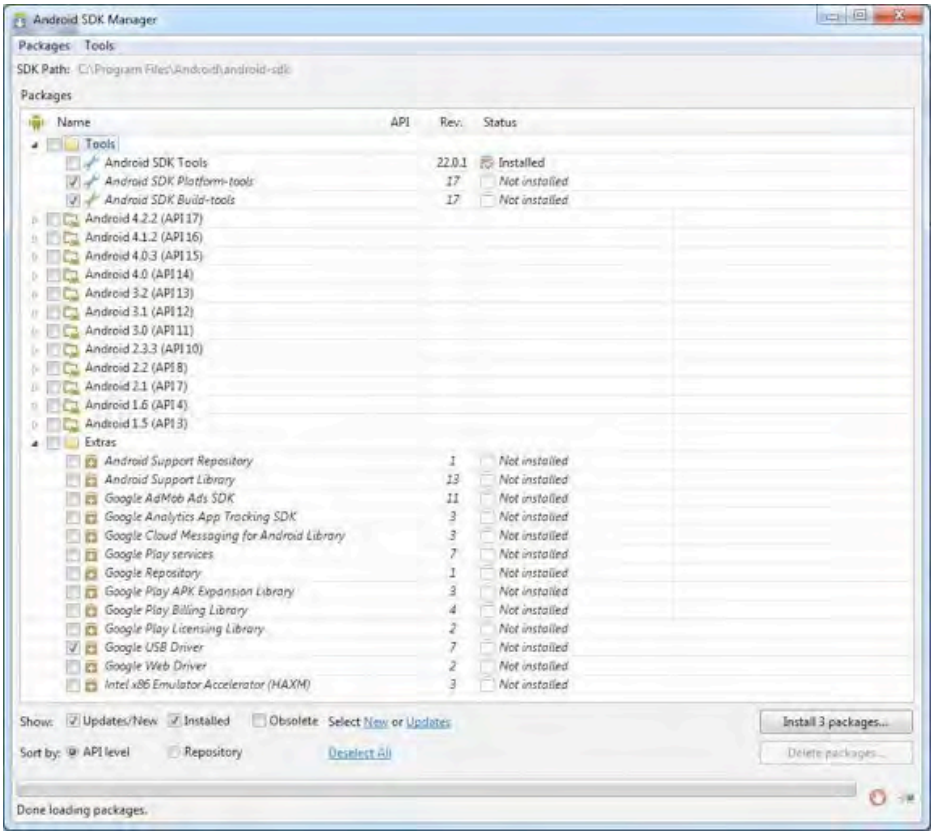



Figure 13

## Step 8


**Install the DANA Data Manager application on the data management PC.**

Note: Java JDK installation and Android SDK installation must occur prior to the following steps.

In Windows:

1. Launch the "Install DANA Data Manager.exe" file and follow on-screen prompts to install the DANA Data Manager application.

   The DANA Data Manager will now be accessible via the *DANA Data Manager* folder in the *Start* menu.

In Mac OS:

1. Launch (double-click) the "DANA Data Manager.dmg" file.
2. Drag the DANA Data Manager icon to your *Applications* folder when the window in **Figure 14** appears.

   Once the files copy over, the DANA Data Manager will be accessible via the *Applications* folder.


Figure 14

## Step 9

**Configure the Android SDK location.**

If you are opening the DANA Data Manager (DDM) for the first time on a given PC, you will need to tell the DDM where the Android SDK is located on the PC.

1. Open the DANA Data Manager application from the Start menu.
2. Click *Manage Device / Download Data* in the main DDM window.

3. If the *Configure Android SDK Location* window below in **Figure 15** appears, simply click *Select Android SDK Location*, find and select the Android SDK folder (it should be where you saved the SDK previously), and click *OK*.

   Note: The folder you should select may be named "platform-tools" (see **Figure 16** below).

   Note (Windows): If you forget where you installed the SDK, right-click on *SDK Manager* (in the Start menu) and click *Properties*. The window shown in **Figure 17** should appear. If you then click *Find Target...*, the folder enclosing the SDK files should appear on-screen.


Figure 15

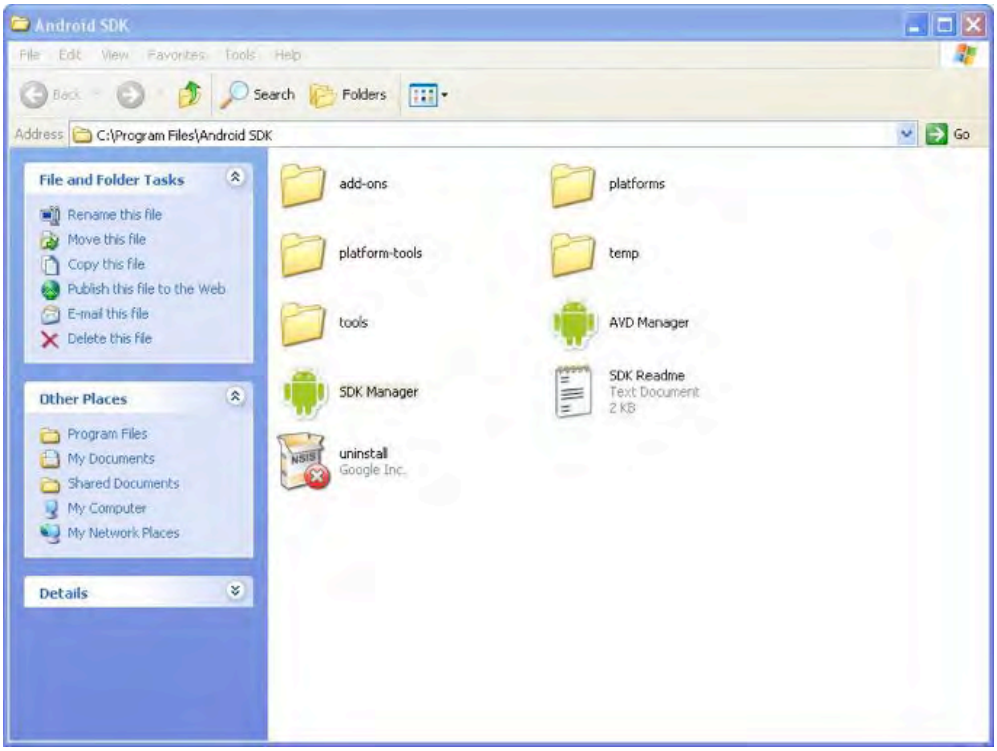



Figure 16


SDK Manager Properties
General
Shortcut
Options
Font
Layout
Colors
Compatibility
SDK Manager
Target type: Application
Target location: Android SDK
Target: \Program Files\Android SDK\SDK Manager.exe"
Start in: "C:\Documents and Settings\user\Start Menu\Pr
Shortcut key: None
Run: Normal window
Comment:
Find Target...
Change Icon...
Advanced...
OK
Cancel
Apply

Figure 17

# Section D – Mobile Device Overview & Setup

This section focuses on the mobile device hardware used to administer DANA.

This hardware can and should vary depending on the context and environment in which it is being used. DANA can be administered in a variety of environments, from a far-forward in-theater position to a neighborhood clinic. Examples of different mobile devices that could be used to administer DANA are displayed below.

**System Recommendations – Mobile Device**
- Operating System: Android API Level 7 or higher (Android 2.1 (Eclair) or better)
- Display: 480x640 (HDPI) or screens 7in (diagonal) or larger

## D-1 Overview

### D-1-1 Important Buttons / Icons

There are a few important buttons on the mobile device that you will need to use frequently while using the DANA System. **Different mobile devices implement these buttons in different ways.** On some mobile devices, they will be physical buttons on a keypad; on others, they will be virtual buttons on the screen. Learn where the following important buttons are for your mobile device.

**Home Button:**
- Brings you to the Home screen.
- Will abort a DANA screening (if one is in progress).

**Menu Button:**
- Brings up quick menus.
- Deactivated during a DANA screening.

**Back Button:**
- Brings you back one level in Android or DANA.
  - This functionality is **deactivated** during a DANA screening (i.e., you cannot go back during a test and change an answer).
- Removes the on-screen keyboard from the screen.


Figure 18

**Power Button:**

- Turns the mobile device on.
- Awakens the mobile device's screen.
- Puts the mobile device's screen to sleep.

Note: If the mobile device is ON, but the screen is asleep, the battery will continue to discharge! Ensure to turn the mobile device completely OFF to best preserve battery life.

## D-1-2 Recommended Settings & Configuration

Certain settings and configurations are recommended to optimize the consistency of data collection.

# Settings

All of the settings for the mobile device can be modified via the Settings menu, which is accessible via the Apps Tray (see **Figure 19**).

**Developer Options:**

- Turn USB debugging ON
  - In the *Developer options* menu, turn *USB debugging* ON. (*Settings* > *Developer options*)
    - If *Developer options* menu is not present, Go to *Settings* > *About device* menu & tap *Build number* seven times in a row. This will enable the *Developer options* menu.

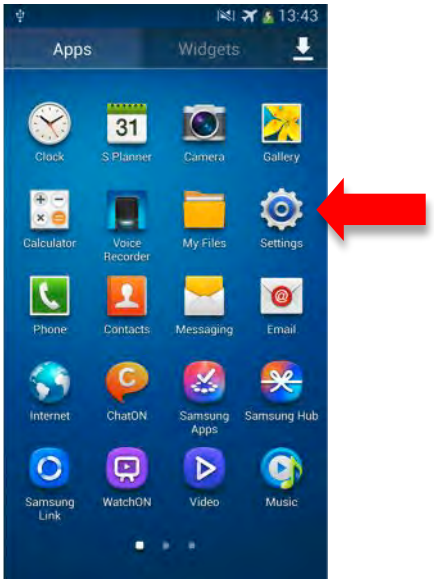



Figure 19

**Account Syncing:**

- Turn any account syncing OFF.

**Communications:**

- Turn *WiFi* OFF.
- Turn *Bluetooth* OFF.
- Turn *Airplane Mode* ON.

**Display:**

- Set Brightness to maximum.
- Turn Automatic brightness OFF.

**Home Screen Cleared:**

- Clear every home screen of content
  - Select and hold each piece of content on the Home screen & drag it to the trash.

**Date and Time:**

- Ensure that the date, time zone, and time are set correctly (go to *Settings* > *Date and time*).

---

# Configuration

**No Protective Case**
**No Screen Protector**
**No Attached Accessories or Cables**

## D-1-3 DANA Personnel Roles

Three main classifications are given to people involved in using the DANA system: (i) Administrator, (ii) Examiner, and (iii) Subject.

The Administrator classification exists in order to allow multiple people to access collected data without sharing a single password (e.g., A Corpsman (Examiner) administers DANA Rapid to a Marine; later, the doctor at the battallion aid station (BAS) wants to examine the subject's results.) This festure is achieved via a keystore algorithm, which adds flexibility while maintaining security. More information on Administrators and the keystore algorithm is provided in **Section D-2 – Step 2** – *Create 1 or more Administrators*.

The figure below captures the major differences and similarities among the main DANA personnel classifications.

| | Administrator (with Full Key) | Administrator (with Delegate Key) | Examiner | Subject |
|---|---|---|---|---|
| Can collect data from subjects | ● (if also an Examiner) | ● (if also an Examiner) | ● | |
| Can log into DANA & view test results on mobile computer | ● (if also an Examiner) | ● (if also an Examiner) | ● | |
| Can transfer test data from mobile computer to PC | ● | | | |
| Can open test data on PC | ● | | | |
| Multiple can exist on 1 mobile computer | | ● | ● | |
| Password is saved on mobile computer | | ● | | |
| Password is saved on PC | ● | | | |
| Can be the same person | ● | ● | ● | |

Figure 20

### Background:

An *Administrator* must be created and added to the mobile device prior to administering any DANA test batteries. *Administrator* is the top-level classification given to data management personnel. There are two statuses a given Administrator can have: *Full* and *Delegate*.

- *Full Administrator* status means the Administrator is capable of encrypting and decrypting collected data (i.e., collecting data, reading all collected data, and transferring data from a mobile device to a PC).
- *Delegate Administrator* status means the Administrator is capable of encrypting data (i.e., collecting data) but not decrypting data (i.e., opening / reading data).

DANA incorporates these two statuses for Administrators for data security purposes. This is achieved by utilizing public key cryptography, which utilizes electronic documents that use secure digital signatures to match each key to a person's (Administrator's) identity. These keys, or *DANA Administrator Keys*, are stored in a DANA key store created by the DANA Data Manager. There are two types of Administrator

Keys: *Full* and *Delegate*, which correspond to Full Administrator status and Delegate Administrator status, respectively. DANA Administrator Keys are RSA keys, each consisting of two portions, a private and a public portion. A *Delegate Key* is only the public portion of an Administrator Key. The private portion of the Administrator Key is only used / stored in the *Full Key*. *Delegate Keys* are therefore exported from *Full Keys*.

The following is an example of the system's utility:

> *Alice and Bob both want to be able to collect data with DANA and both have access to the data. However, Alice and Bob are far apart and can only communicate via insecure channels. Therefore, Alice creates a Full Administrator Key. If she were then to send the Full Key to Bob, someone could possibly decode it and get access to any data collected. Instead, Alice exports a Delegate Key from the Full Key and sends this Delegate Key to Bob. Bob then installs the Delegate Key on his mobile device and collects some data. Then Bob sends these data back to Alice, and she is able to open and manage the datasets.*
> *(Accordingly, Bob and Alice could switch roles in order to share data in the opposite direction.)*

An additional, lower-tier classification utilized by DANA is the *Examiner* classification (discussed below in **Section D-2 – Step 5**). The *Examiner* classification is given to personnel who administer DANA test batteries. Examiners only have access to data **they** collect themselves. Personnel can be classified as both Examiners and Administrators, if desired.

*Administrator* and *Examiner* classifications exist in order to allow data collected in the field by Examiners (Corpsmen / Medics) to be read by Administrators (e.g., Senior Medical Officers). Multiple Administrators and Examiners can be present on the same mobile device.

# D-2 Setup

## Step 1

**Install DANA.**

Note: Before installing DANA, first check if a version of DANA is already installed. If so, you should uninstall it before installing the correct version. **UNINSTALLING DANA WILL PERMANENTLY ERASE ALL COLLECTED DATA, ADMINISTRATORS, EXAMINERS, AND SUBJECTS FROM THE MOBILE DEVICE!** To uninstall DANA, enter the Settings menu, select Applications, then Manage Applications, then DANA. Select Uninstall and confirm the action in any windows that may pop up.

*Only needs to be done once (per mobile device).*

1. Turn the mobile device ON, unlock the screen, and plug it into the data management PC with the USB cable provided.
2. Launch the DANA Data Manager (DDM) on the data management PC.
3. Click *Manage Device / Download Data* in the DDM main screen (see **Figure 21** below). A new window should appear.
4. Click *Install DANA* in the new DDM window (see **Figure 22** below).
5. Locate and select the correct DANA_Android.apk file and click *Open*.


Figure 21


Figure 22

## Step 2

### Create 1 or more Administrators.

*Only needs to be done once.*

Note: Administrator rights are needed to transfer data to a PC, open datasets on the PC, and set up a mobile device. Multiple Administrators may be created to allow multiple people to do these tasks (without sharing a password). All Administrators must be created during this initial setup process, so make sure to create all Administrators necessary during this step.

1. Launch the DANA Data Manager (DDM) application on your data management PC.
2. Click Manage Administrators in the main DDM window (**Figure 21**). A new DANA Administrator Manager window should appear (**Figure 23**).
3. In this new window, click *Create Administrator*.
4. Enter a name for the Administrator and click *Create*.
5. Navigate to the location on your Data Management PC where you want to save the Administrator Key Store file, enter a name for the file, and click *Save*. This will be the name of the file on your PC that holds the *Administrator Key* for this Administrator.

   Note: The Administrator and Administrator Key Store need not have the same name.
6. Enter and re-enter the password for this Administrator and click *OK*.

   Note: Remember this password. You will need to enter it each time the Administrator is opened.
7. Close the *DANA Administrator Manager* window.

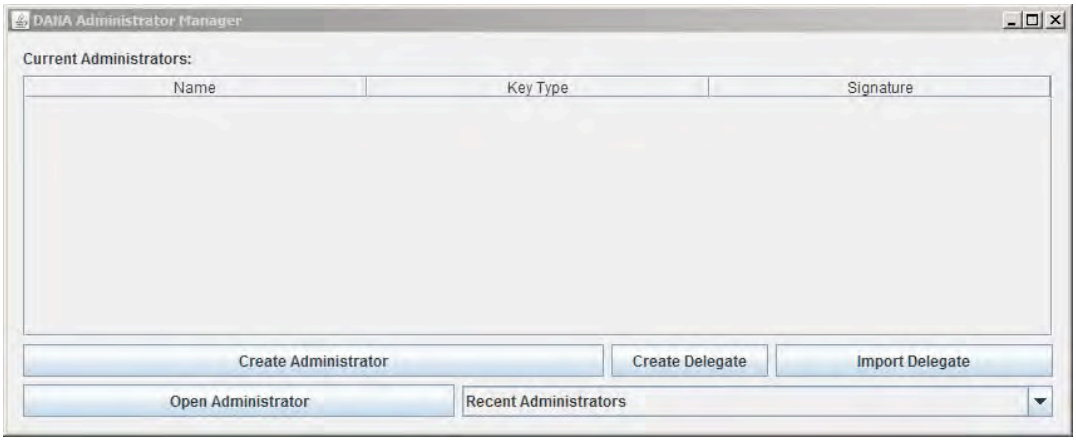



Figure 23

### Creating a Delegate Administrator:

Note: A Delegate Administrator is an Administrator with limited permissions. A Delegate can encrypt (i.e., collect) data but not decrypt (i.e., open or read) data.)

1. In the DANA Administrator Manager window (**Figure 23**), select the Administrator for which you want to create a Delegate.
2. Click *Create Delegate*, select where you want to save the delegate file on the PC, and click *Save*.

## Step 3

### Add your Administrator(s) to the mobile device.

*Only needs to be done once (per mobile device)*.

Note 1: If continuing directly from **Step 1** (above) with the same mobile device, skip to **step 7** below.

Note 2: Make sure to add all Administrators necessary at this time. Administrators may not be added at a later time without uninstalling DANA and erasing all data from the mobile device. Administrator rights are needed to transfer data to a PC, open datasets on the PC, and set up a mobile device.

1. Launch the DANA Data Manager application on your data management PC (if it is not open already).
2. Turn on the mobile device, unlock the screen, and plug the mobile device into the data management PC via its USB cable. Make sure the mobile device's screen remains awake.
3. Launch DANA on the mobile device (from the Apps Tray).
4. Once at the DANA Login screen, press the Menu button and select *Manage Device* from the menu that pops up.
5. In the DANA Data Manager, click *Manage Device / Download Data*. The window in **Figure 24** should appear. If the window in **Figure 25** appears instead, click *Connect to device*. This should bring you to the window in **Figure 24**. If it fails again, press the Back button on the mobile device (to return to the Login screen), close and re-launch the DANA Data Manager, and repeat **steps 4-5** (above).
6. Click *Load/Create Local Administrators*.

- If the Administrator you want to use is not listed in the *DANA Administrator Manager* window that appears, click *Open Administrator*, locate and select the desired Administrator key store, and click *Open*.
- If the Administrator you want to use is listed in the *DANA Administrator Manager* window that appears, close this window.

7. In the *Manage Device / Import Data* window (**Figure 24**), click *Add Administrator*. A new window should appear displaying available Administrators to add (**Figure 26**).
8. Choose the desired Administrator(s) from the list and click *Ok*.
9. Once opened, the Administrator should appear in the DANA Administrator Manager window, as in **Figure 27**.

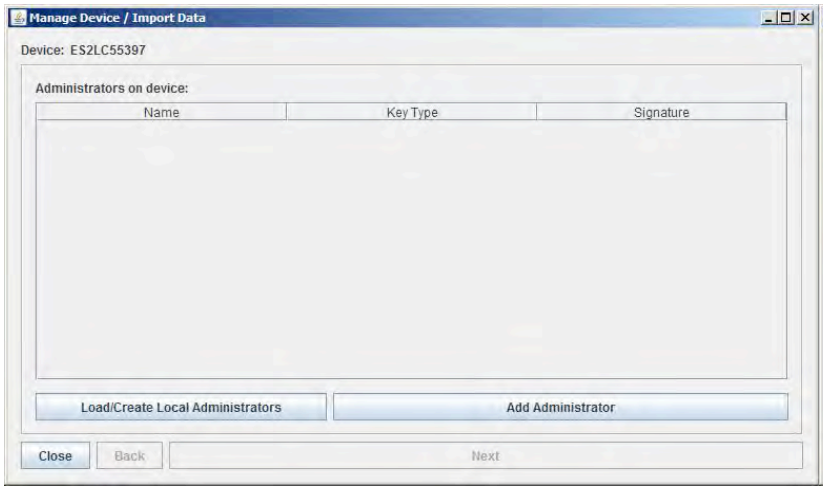



Figure 24


Figure 25

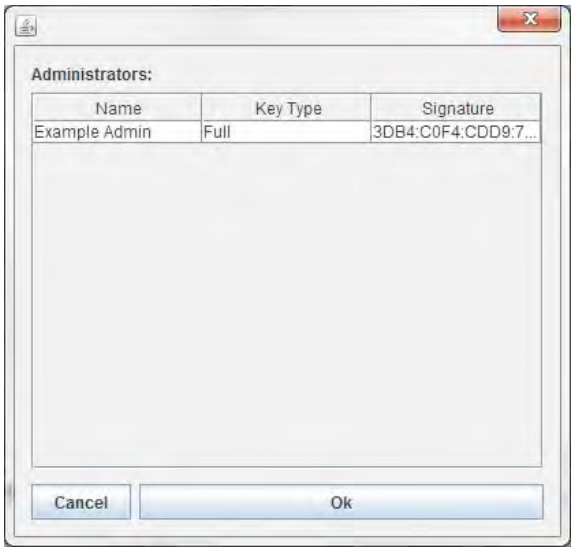



Figure 26

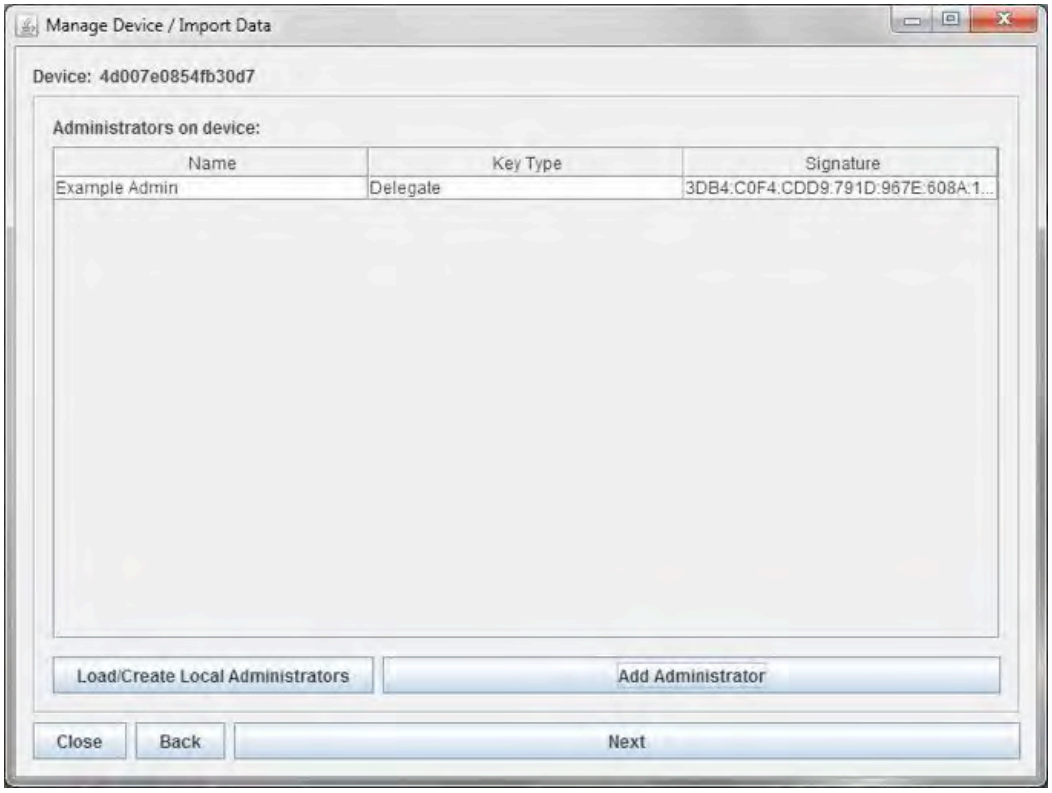



Figure 27

### Importing a Delegate Administrator:

Note: A Delegate Administrator is an Administrator with limited permissions. A Delegate can encrypt (i.e., collect) data but not decrypt (i.e., open or read) data.)

1. From the DANA Administrator Manager window, click *Import Delegate*.
2. Select the Administrator Key Store to contain the imported Delegate, then click *Open*.
3. Click *Create* and choose where you want to save the imported Delegate, then click *Save*.
4. You will then be prompted to create a password. Click *OK* when finished creating the password.

## Step 4

### Add test batteries to the mobile device.

*This step only needs to be done once (per mobile device).*

1. Click *Load Test Battery Package* in the *Manage Device / Import Data* window of the DANA Data Manager (**Figure 28**).
2. Select the desired DANA battery package file (file should end in ".DANABatteryPackage") and click *Open*.
3. Click *Next* in the *Manage Device / Import Data* window.

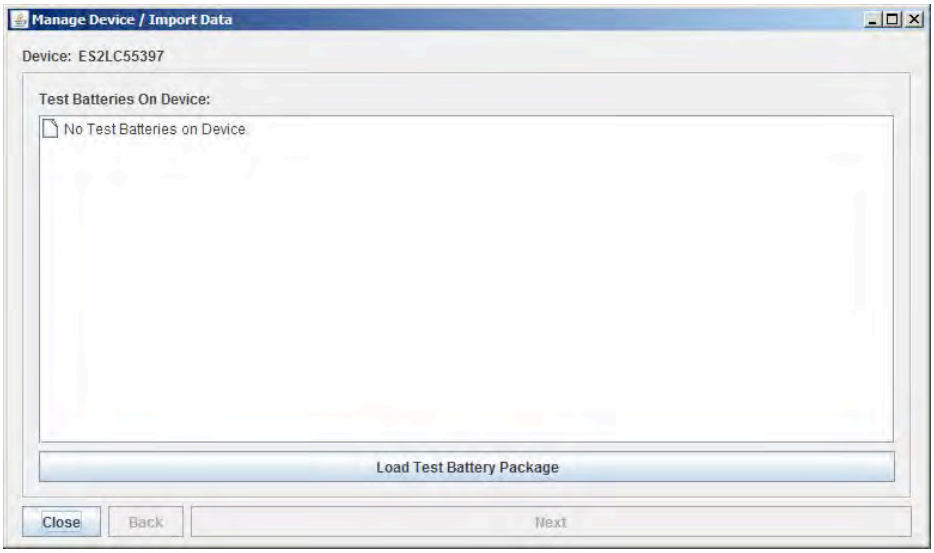



Figure 28

**Before continuing with Step 5, ensure that you have added all of the Administrators you want to the mobile device. Once you create an Examiner, you will not be able to add any other Administrators to the mobile device.**

## Step 5

### Create a new Examiner.

*Only needs to be done once (per mobile device)*.

**Option 1** – Using the DANA Data Manager:

1. Click *Add New Examiner* in the *Manage Device / Import Data* window of the DANA Data Manager.
2. Enter a name and password for this Examiner and click *Create Examiner* (**Figure 29**). The Examiner should now appear in the *Manage Device / Import Data* window.
   The Examiner is the person who will administer tests to service members.
3. Click *Close* in the *Manage Device / Import Data* window.
4. Quit the DANA Data Manager application, if desired.

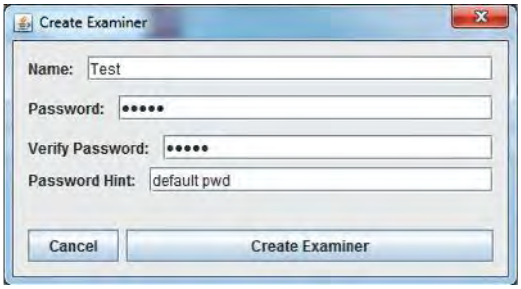



Figure 29

**Option 2** – Not Using the DANA Data Manager (**Figure 30**):

1. Launch DANA on the mobile device.
2. At the Login screen, press the Menu button and select *Create Examiner* from the menu that pops up.
3. Enter the Examiner's name and password and select *Save*.

Note 1: The Examiner password must be at least 5 characters in length.

Note 2: Remember this name and password. You will need to enter them each time you log into DANA.

The mobile device should now be completely set up for collecting data. Repeat the steps in this section for each mobile device you wish to set up.

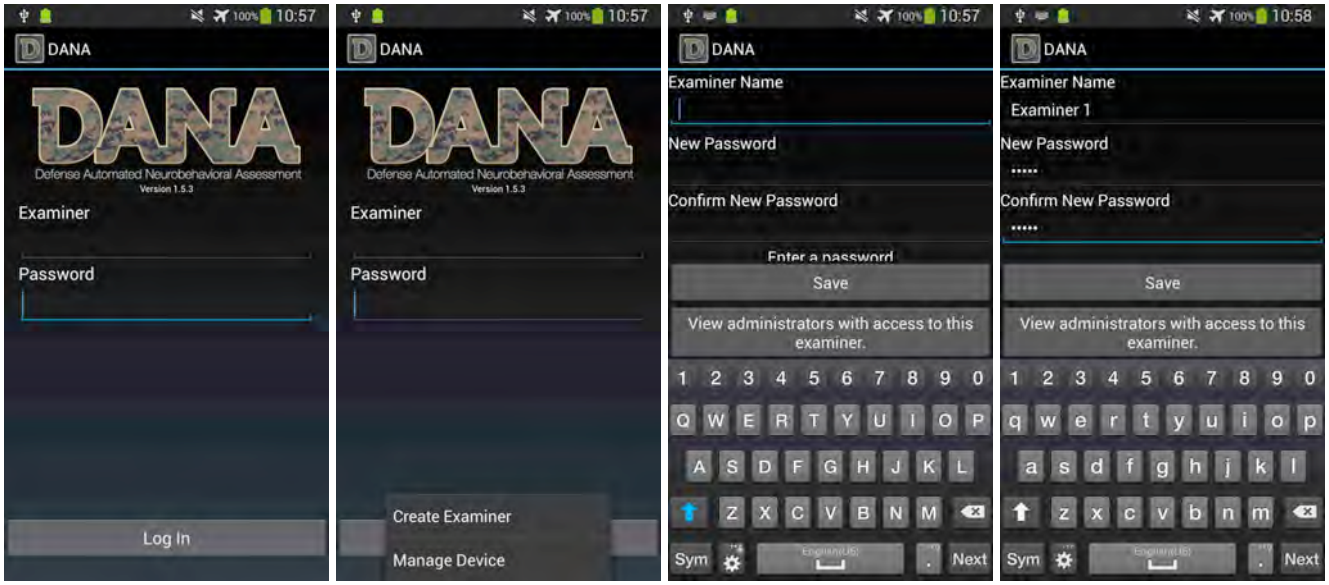



Figure 30

# Section E – Using DANA

Detailed steps for configuring and using DANA are listed below. Depending on the specific type of mobile device you are using to run and administer DANA, some of the steps and figures below may vary. See the user guide for your specific mobile device for further help. Unless otherwise specified, the instructions below pertain to the Trimble Nomad mobile device and a data management PC running the Windows 7 operating system.

## E-1 Administering a Screening to a Subject

1. **Launch DANA** – Turn on the mobile computer, press the Home (to arrive at the Home screen), and then launch DANA (from the Apps Tray).
2. **Log In** – Log in using the Examiner credentials created previously (**Figure 31**).
3. **Select an Existing Subject or Create a New One:**
   - To select an existing Subject, select the desired Subject from the list.
   - To create a new Subject, select *Add a New Person*, enter information for a Subject, and select *Create New Person* (**Figure 32**).

     Note 1: Selecting the *Injured* box allows you to enter the date and time of an injury.

     Note 2: You only need to fill in the *Name* field to create a new Subject. The other fields are optional.

     Note 3: To edit an existing Subject's information, select the Subject, then press the Menu button and select *Edit Patient*..." (**Figure 33**).

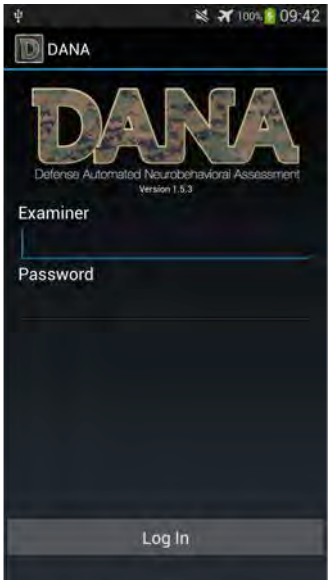



Figure 31

4. **Select & Start a Screening** – Select a screening from the list, select *Start New Screening* (**Figure 34**), and hand the mobile computer to the Subject to start the screening.
5. **Select *Screening Completed*** – At the end of a screening, select *Screening Completed* at the bottom of the screen, if the Subject has not done so already.
   The Examiner will be logged out at this point (for data security purposes).

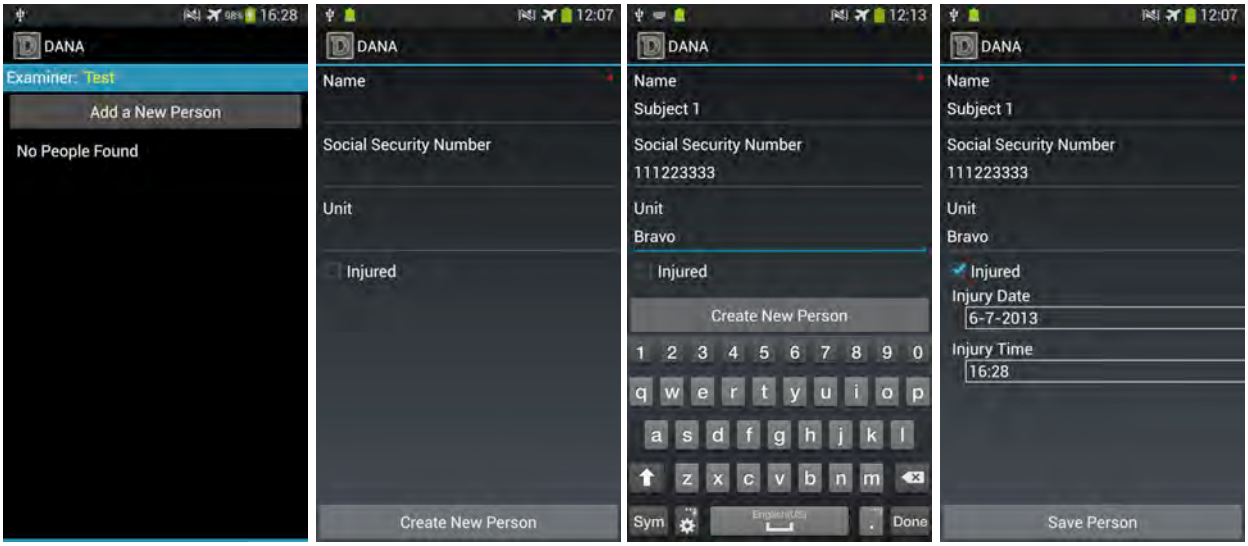



Figure 32

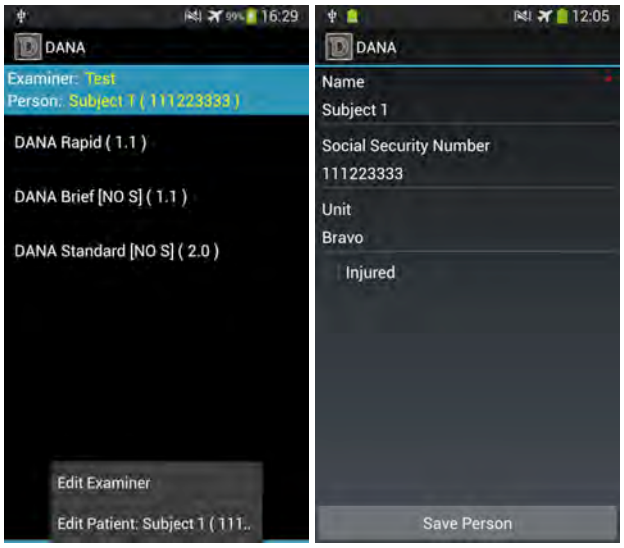



Figure 33

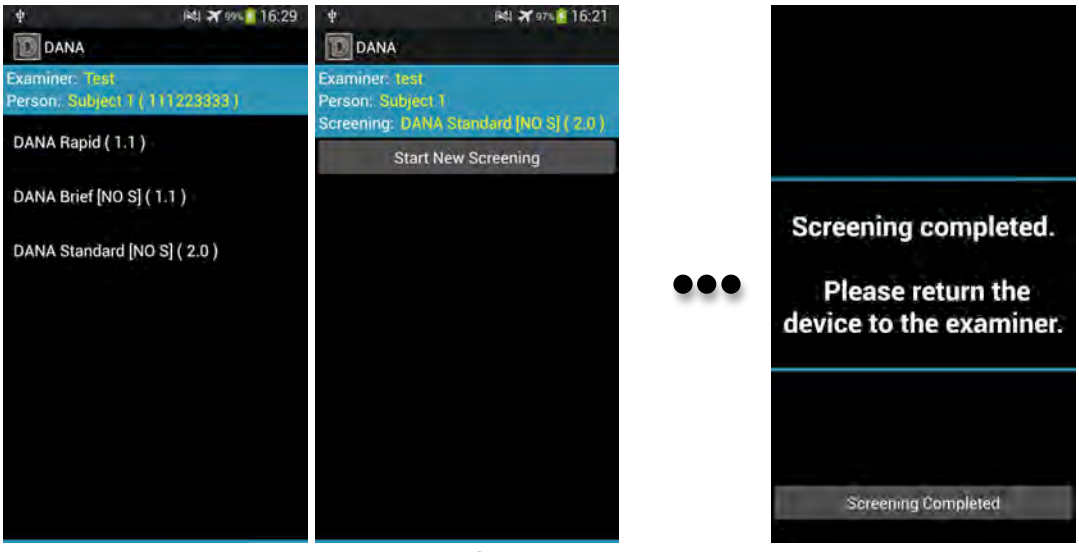


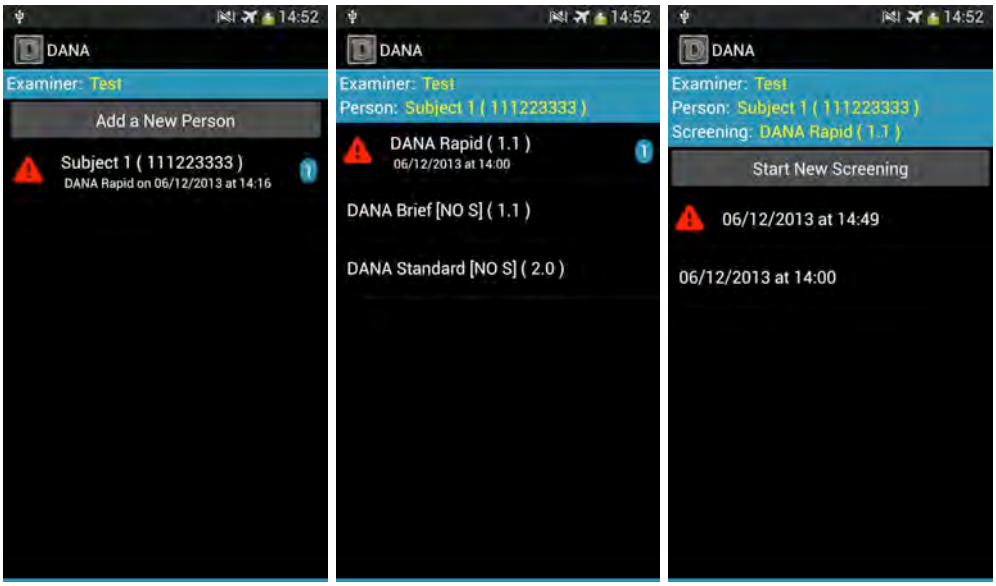

Figure 34

# E-2 Resuming or Discarding an Aborted Screening

DANA has a feature that allows an Examiner to resume a screening that has been aborted (while in progress) for any reason (e.g., device failure, device getting turned off, Home button press). Once the Examiner logs back into DANA, they will be brought to the Staging Screen. To resume the aborted screening:

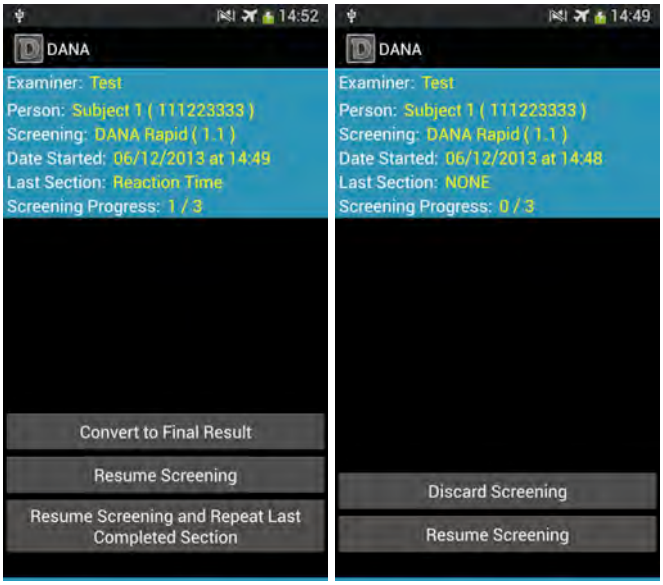
1. Select the Subject who aborted their screening from the Staging Screen (**Figure 35a)**.
   Note: All Subjects who have aborted a screening & screenings that have been aborted will have a red triangle icon next to them.
2. Select the screening type that was aborted (**Figure 35b**).
3. Select the individual screening that was aborted (**Figure 35c**).
4. The next screen will appear either as in **Figure 36a** or **36b**, providing a summary of the aborted screening, and offering test resume options:
   - If at least one section of the screening has been completed, this screen (**Figure 36a**) will offer three resume options:
     i. *Resume Screening and Repeat Last Completed Section*,
     ii. *Resume Screening*, and
     iii. *Convert to final result*.
   - If no sections of the screening have been completed, this screen (**Figure 36b**) will simply provide two options:
     i. *Resume Screening*, and
     ii. *Discard screening*.

   Selecting *Discard screening* will discard the entire screening that was aborted and return the Examiner back to the Staging screen. The Examiner can then set up a new screening from this screen.




a b c

Figure 35




a b

Figure 36

# E-3 Viewing Screening Results on the Mobile Device

Once a screening is completed, results are automatically calculated and a report is generated by DANA on the mobile device. To view this report:

1. If a Subject has just concluded a screening, collect the mobile device from the Subject and select *Screening Completed* (if the Subject has not already).
2. Log into DANA.
3. Select the Subject from the list whose test results you want to view (if the Subject is not already selected).
4. Select the test battery you want to see results for (if not already selected).
5. Select the appropriate individual screening (**Figure 37**). The *Report Summary* screen should now load (**Figure 37)**. Scroll down to see the entire screen.
6. Press the Menu button and select other report sections (e.g., *Cognitive Sections Details*) and then select an individual test (e.g., *Procedural Reaction Time*) to see individual test results (**Figures 38 and 39**).

   Note: For most test batteries, the individual test sections are embedded within either the *Cognitive Sections Details* or *Psychological Sections Details* menu. Select one of these menu options and then select the individual test to access these reports.

To return to the Staging screen, press the *Back* button.

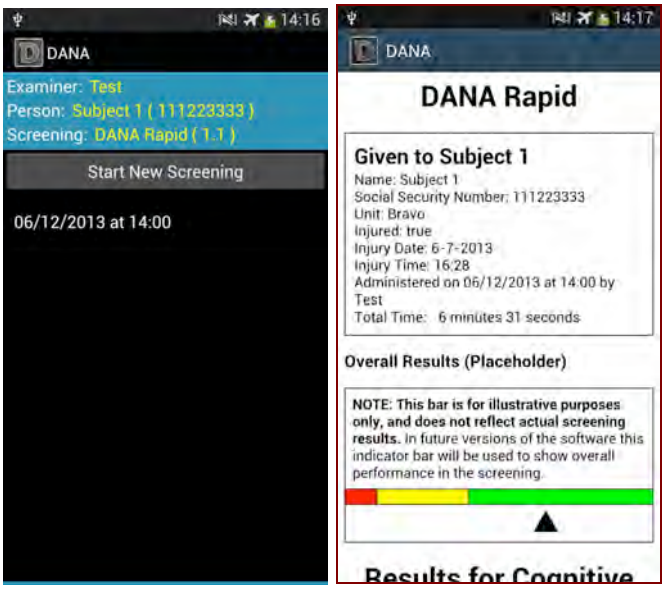



Figure 37

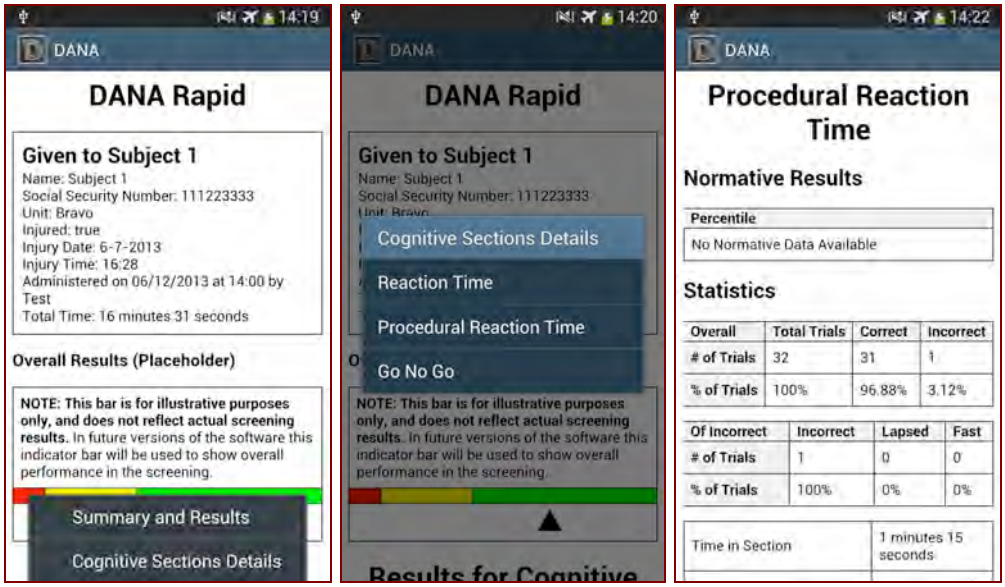



Figure 38

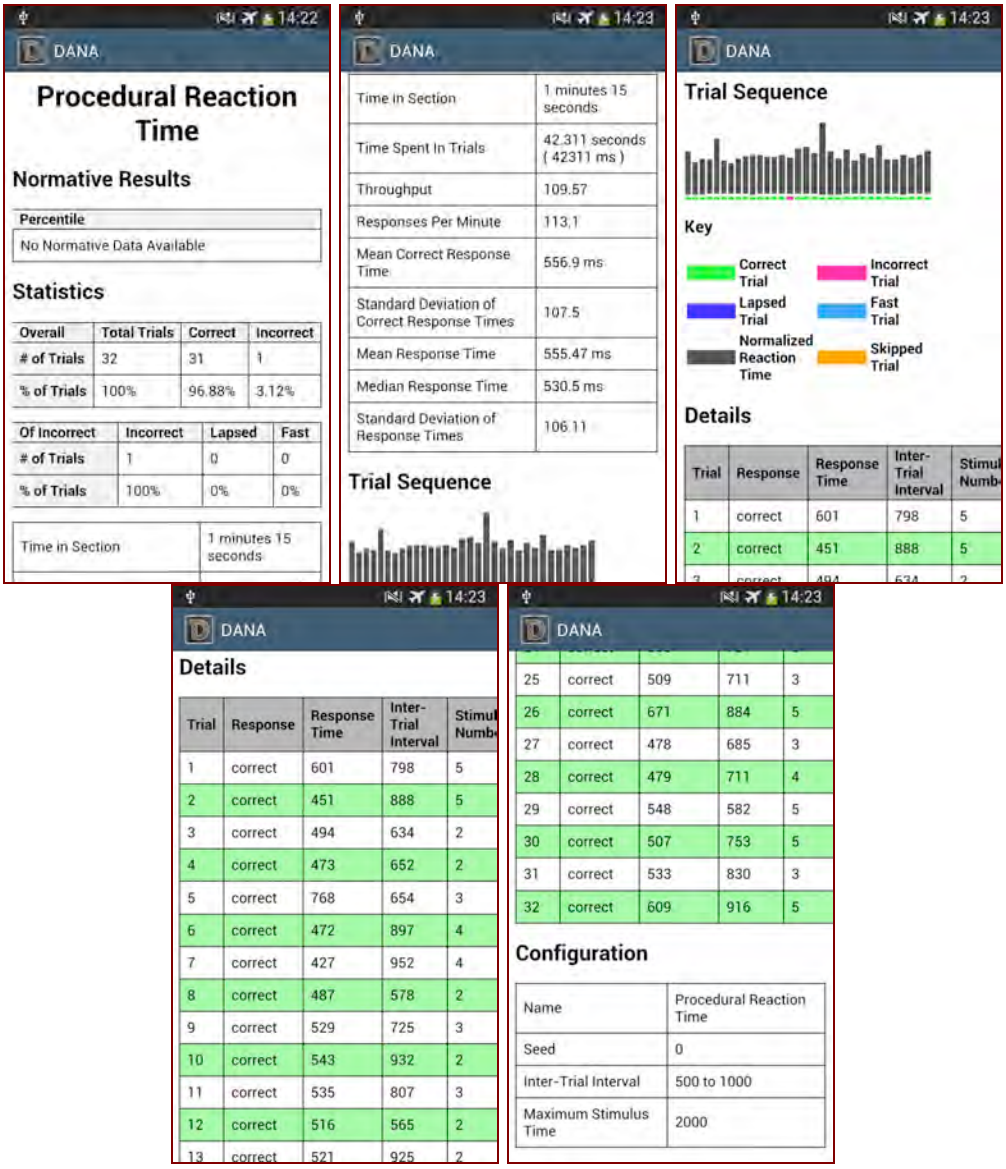

14:22
DANA
Procedural Reaction Time
Normative Results
Percentile
No Normative Data Available
Statistics
Overall | Total Trials | Correct | Incorrect
# of Trials | 32 | 31 | 1
% of Trials | 100% | 96.88% | 3.12%
Of Incorrect | Incorrect | Lapsed | Fast
# of Trials | 1 | 0 | 0
% of Trials | 100% | 0% | 0%
Time in Section | 1 minutes 15 seconds
14:23
DANA
Time in Section | 1 minutes 15 seconds
Time Spent In Trials | 42.311 seconds ( 42311 ms )
Throughput | 109.57
Responses Per Minute | 113.1
Mean Correct Response Time | 556.9 ms
Standard Deviation of Correct Response Times | 107.5
Mean Response Time | 555.47 ms
Median Response Time | 530.5 ms
Standard Deviation of Response Times | 106.11
Trial Sequence
14:23
DANA
Trial Sequence
Key
Correct Trial
Incorrect Trial
Lapsed Trial
Fast Trial
Normalized Reaction Time
Skipped Trial
Details
Trial | Response | Response Time | Inter-Trial Interval | Stimul Numb
1 | correct | 601 | 798 | 5
2 | correct | 451 | 888 | 5
14:23
DANA
Details
Trial | Response | Response Time | Inter-Trial Interval | Stimul Numb
1 | correct | 601 | 798 | 5
2 | correct | 451 | 888 | 5
3 | correct | 494 | 634 | 2
4 | correct | 473 | 652 | 2
5 | correct | 768 | 654 | 3
6 | correct | 472 | 897 | 4
7 | correct | 427 | 952 | 4
8 | correct | 487 | 578 | 2
9 | correct | 529 | 725 | 3
10 | correct | 543 | 932 | 2
11 | correct | 535 | 807 | 3
12 | correct | 516 | 565 | 2
13 | correct | 521 | 925 | 2
14:23
DANA
25 | correct | 509 | 711 | 3
26 | correct | 671 | 884 | 5
27 | correct | 478 | 685 | 3
28 | correct | 479 | 711 | 4
29 | correct | 548 | 582 | 5
30 | correct | 507 | 753 | 5
31 | correct | 533 | 830 | 3
32 | correct | 609 | 916 | 5
Configuration
Name | Procedural Reaction Time
Seed | 0
Inter-Trial Interval | 500 to 1000
Maximum Stimulus Time | 2000

Figure 39

# E-4 Transferring Screening Data to the Data Management PC

Data from a completed screening (or multiple completed screenings) must be transferred to a PC from the mobile device in order to then export the data into a usable format (e.g., CSV, PDF) for data analysis or PDF report generation.

Follow these instructions to transfer screening data from the mobile device to the data management PC:

1. Turn the mobile device on and unlock the screen.
2. Connect the mobile device to the data management PC via the USB cable.
3. Go to the Home screen, and then launch the DANA application.
4. Once at the DANA Login screen, press / select *Menu*, then select *Manage Device / Transfer Data* in the menu that appears (**Figure 40**).

   Note: The *Manage Device / Transfer Data* option is deactivated at the Login screen displayed in **Figure 41** (which appears immediately after completion of a screening). From that screen, press / select *Back* or select *Log In as another Examiner* to reach the Login screen in **Figure 40**.
5. On the PC, launch the DANA Data Manager (DDM) application, if it is not already running.
6. In the DANA Data Manager window, click *Manage Administrators*.
7. If the Administrator overseeing the data you want to transfer is not listed in the subsequent window, click *Open Administrator*, locate and select the appropriate Administrator Key Store, and click *Open*.

   Note: You can also open a recently opened Administrator via the *Recent Administrators* drop-down menu in the DANA Administrator Manager window.
8. Log in with the Administrator's password and close the DANA Administrator Manager window.
9. Click *Manage Device / Download Data* in the main DDM window. Shortly thereafter, a *Manage Device / Import Data* window should appear.
   - If the DDM has successfully paired with the mobile device, the DDM's *Manage Device / Import Data* window will appear as in **Figure 42** below.
   - If the DDM did not successfully pair with the mobile device, the DDM's *Manage Device / Import Data* window will appear as in **Figure 43** below. If this is the case, press / select *Back* on the mobile device (to reach the DANA login screen), repeat **step 3** above, and (in the DDM) click *Connect to device*. If this does not work, close the DDM, press / select Back on the mobile device (to reach the DANA login screen), and repeat Steps 3-8 above.
10. Once the DDM's *Manage Device / Import Data* window appears as in **Figure 42**, select the Examiners from the list whose collected data you want to transfer and click *Transfer Data For Selected Examiners*.

    Note: By default, a copy of all the data will remain on the mobile device after the transfer to the PC. To permanently remove the data from the mobile device as part of the transfer


Figure 40


Figure 41

process, deselect the checkbox next to *Keep data on device after transfer* prior to transferring the data.

11. Select the location where you want to save the data on the PC and click *Save*.
12. Click *OK* to acknowledge that that transfer completed successfully.

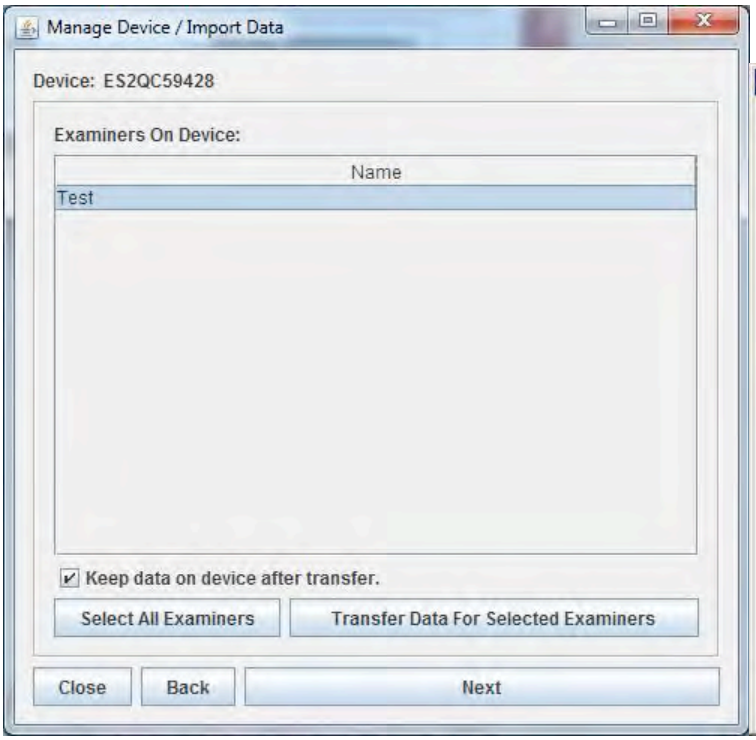



Figure 42


Figure 43

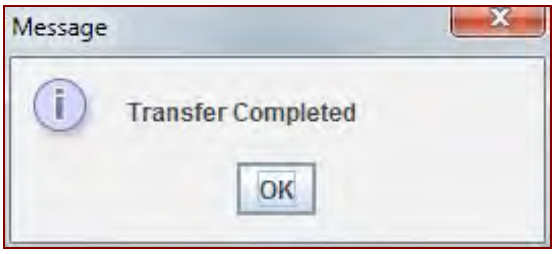



Figure 44

# E-5 Viewing Screening Results on the Data Management PC

1. In the DANA Data Manager (DDM), click *Open Dataset,* select the desired DANABase file, and click *Open*.
2. If prompted, enter the password for the Examiner under whom the data was collected and click *Open*. (If an Administrator is logged in on the PC, no additional Examiner login will be required.)
3. The DANA Viewer will appear on-screen (**Figure 45**).
4. The default view option for the left panel (*Screenings* and *Patients*) is the Tree view. In Tree view, the *Screenings* and *Patients* folders can be expanded by double-clicking on them. The

other view option is Table view (**Figure 46**). In Table view, Subjects (or Patients) are listed one-by-one, organized by screening type.

5. Select an individual screening in this left panel to display the screening report in the right panel.

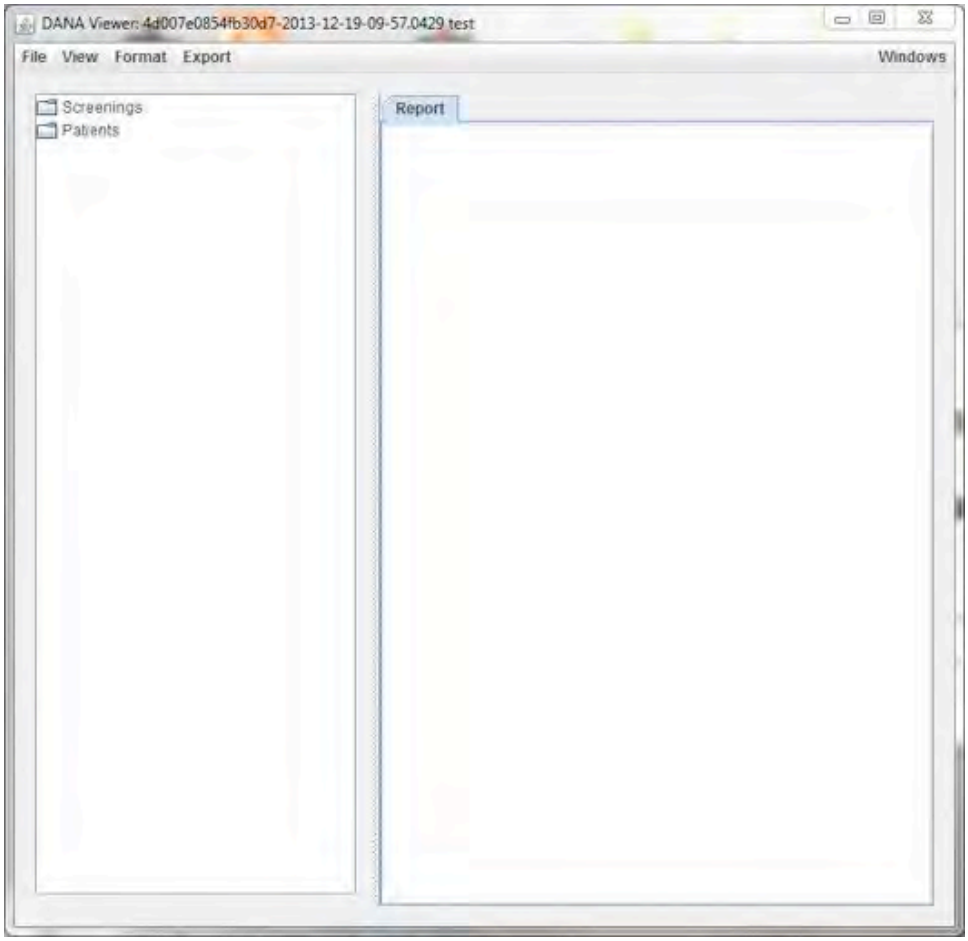



Figure 45

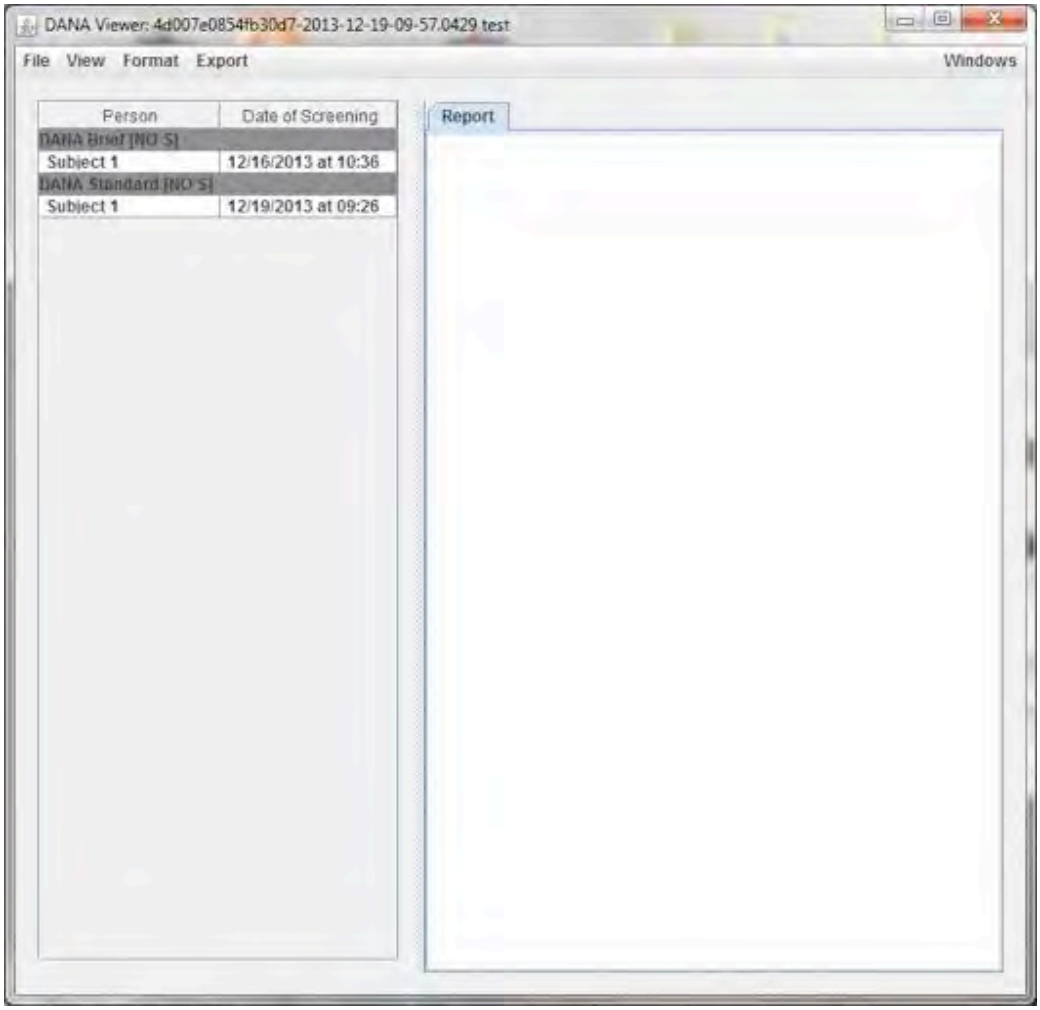

DANA Viewer: 4d007e0854fb30d7-2013-12-19-09-57.0429 test
File View Format Export
Windows
Person
Date of Screening
DANA Brief [NO S]
Subject 1
12/16/2013 at 10:36
DANA Standard [NO S]
Subject 1
12/19/2013 at 09:26
Report

Figure 46

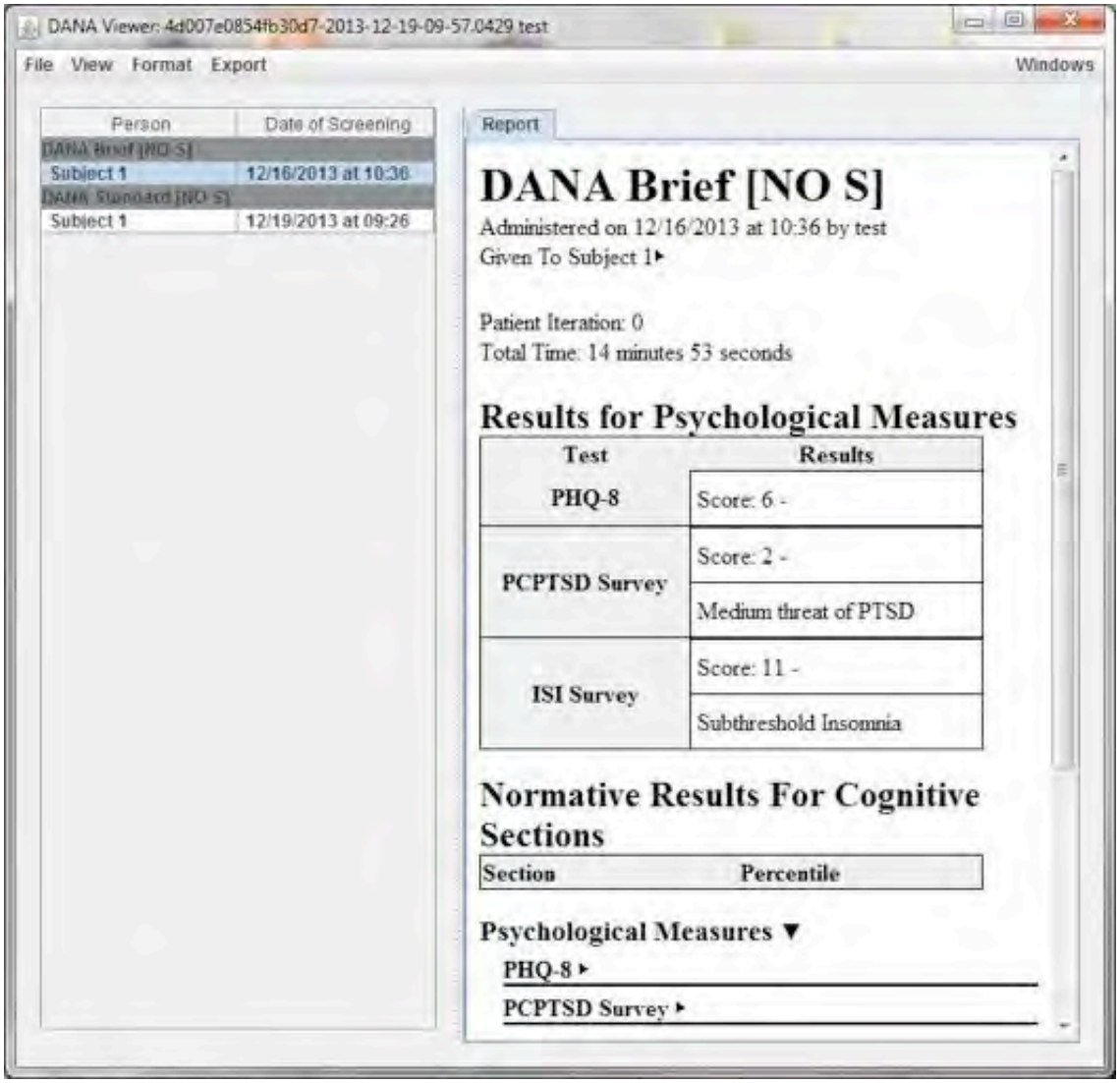

DANA Viewer: 4d007e0854fb30d7-2013-12-19-09-57.0429 test
File View Format Export
Windows
Person
Date of Screening
DANA Brief [NO S]
Subject 1
12/16/2013 at 10:36
DANA Standard [NO S]
Subject 1
12/19/2013 at 09:26
Report
DANA Brief [NO S]
Administered on 12/16/2013 at 10:36 by test
Given To Subject 1
Patient Iteration: 0
Total Time: 14 minutes 53 seconds
Results for Psychological Measures
Test
Results
PHQ-8
Score: 6 -
PCPTSD Survey
Score: 2 -
Medium threat of PTSD
ISI Survey
Score: 11 -
Subthreshold Insomnia
Normative Results For Cognitive Sections
Section
Percentile
Psychological Measures
PHQ-8
PCPTSD Survey

Figure 47

# E-6 Exporting Transferred Data in Usable Formats

Data within DANABase files that have been transferred to a PC can be exported into different, more usable formats such as PDF or CSV for easier data organization and analysis. For example, CSV files can be easily imported into a Microsoft Excel spreadsheet.

**The following export options are available:**

Table 1

| Export Option | File Format | Files Generated | Cognitive Test Data Included? | Psycho-logical Test Data Included? | Trial-by-Trial Data Included? | Notes |
|---|---|---|---|---|---|---|
| XML | XML | (See Notes) | Yes | Yes | Yes | One file per test per Subject |
| Full Report | HTML | (See Notes) | Yes | Yes | Yes | One file per test per Subject |
| PDF Report | PDF | (See Notes) | Yes | Yes | Yes | One file per test per Subject |
| Test Statistics | CSV | 3-7 | Yes | No | No | One file per Cognitive test |
| Test Responses | CSV | 3-7 | Yes | No | Yes | One file per Cognitive test |
| Single Row per Subject | CSV | 1 | Yes | Yes | No | Psychological data includes only scores, not responses |
| Demographics | CSV | 1 | n/a | n/a | Yes (See Notes) | Responses to Demographics Survey |
| Extended Format – User UUID | CSV | 7-25 | Yes | Yes | Yes | Two files per test / survey, plus 1-3 files with overall screening information. |
| Extended Format | CSV | 4-19 | Yes | Yes | Yes | 1-2 files per test / survey, plus three files with overall screening information |
| Finger Tapping Test Export | CSV | 2 | Yes | n/a | Yes | Responses to Finger Tapping Test |
| Raw Balance Data | CSV | 5 per stance | n/a | n/a | n/a | Raw sensor data collected during the Balance test |
| Raw Data | CSV | 13-22 | Yes | Yes | Yes | |

These options are also described in detail in **Appendix A**.

## E-6-1 Exporting data from a single DANABase file

Note: These instructions assume that a Subject has tested and the test data (DANABase file) have been transferred from the mobile device to the data management PC.

1. Launch the DANA Data Manager (DDM).
2. Click *Open Dataset* from the DDM main screen (**Figure 48**), locate the correct DANABase file, and click *Open*.

3. If prompted, log in with the password for the Examiner who originally administered the tests to the Subject. (If an Administrator is logged in on the data management PC, no additional Examiner login will be required.)
4. In the new DDM window that appears, click *View* and then choose your preferred view option (*As Tree* or *As Table*.

   Note: Only the *As Tree* view option permits exporting multiple screenings for 1 subject at once.
5. Select the screening or screenings you want to export, click *Export* from the menu at the top left, and select an export option from the list.

   Note: See **Appendix A** for descriptions of the various export options.
6. Click *Export* in the bottom right of the window, create a file name and save location, and click *Save*.

The screening(s) should now be exported and saved in the chosen location on your PC.

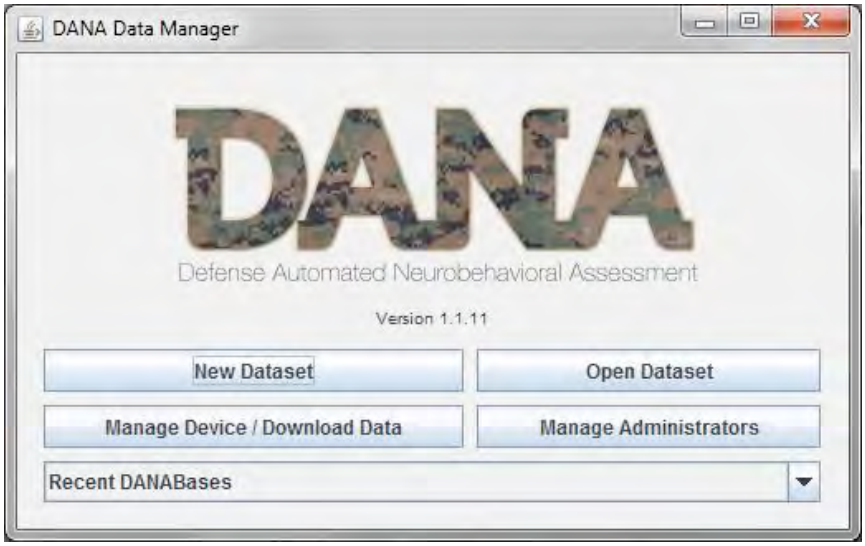



Figure 48

Note: After you complete an export **you will need to click *Close* to close the export panel before attempting a different export (see Figure 49).**

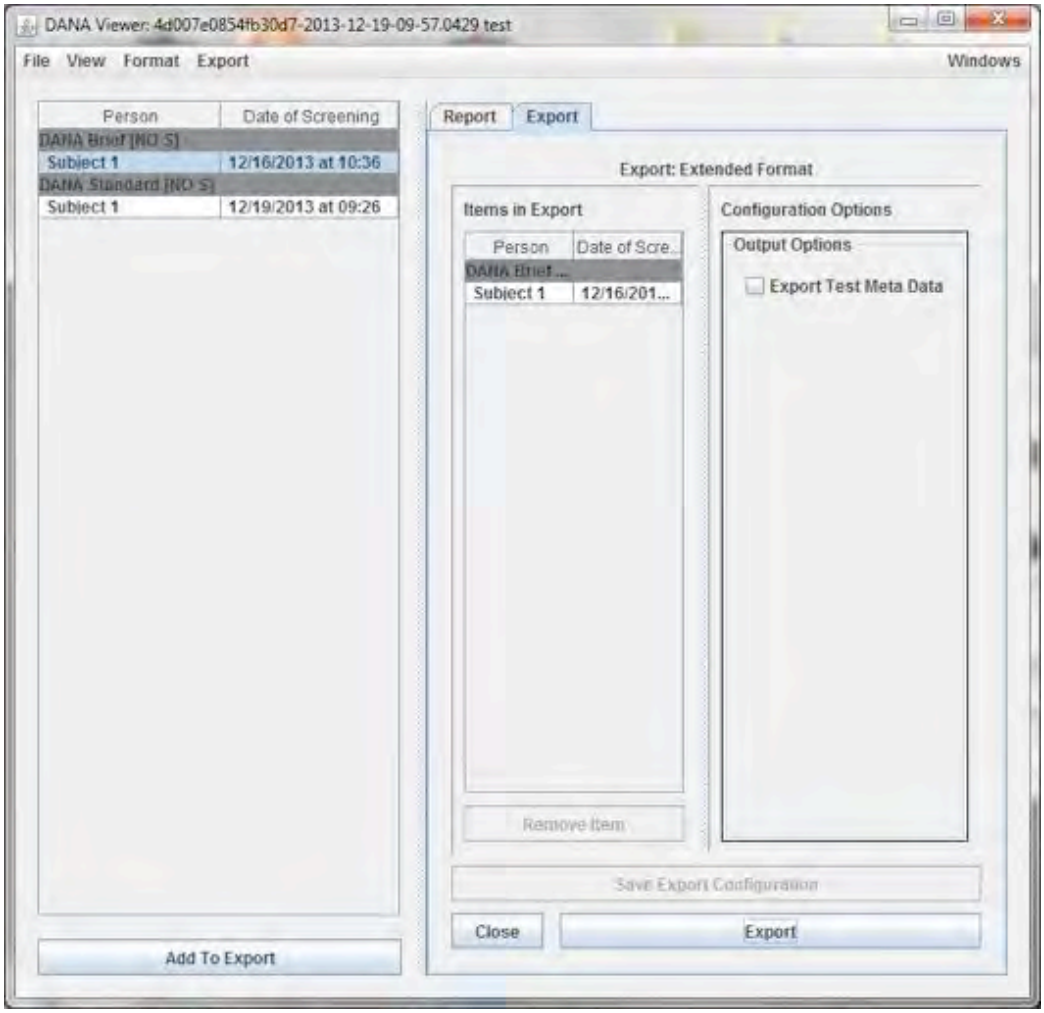



Figure 49

## E-6-2 Combining multiple DANABase files into a single DANABase file

1. Launch the DANA Data Manager (DDM).
2. Click *New Dataset* from the DDM main screen (**Figure 48**).
3. Enter a file name for the DANABase and save it on the PC.
4. Enter a password that will be required to open this DANABase and click *Create*.
5. Click *File*, then *Import Data from local DANABases*.
6. Enter the password for the Examiner who collected the data you wish to import. Then click *Import DANABase*.
7. Select the DANABase files you wish to import and click *Open*. Click *OK* to acknowledge a successful import. If you want to import more DANABase files, simply click *Import DANABase* again, select the additional DANABase files, and click *Open*.
8. Once you have selected and opened all of the DANABase files you want to export, click *Finish and Close*.

## E-6-3 Exporting data from a combined DANABase file

1. From the DDM main screen, click *Open Dataset*. Select the combined DANABase file and click *Open*.
2. Enter the password you created for this DANABase file, and click *Open*.
3. Select as many screenings as you want to export (from the left pane of the DDM window), click *Export*, and then choose the export option from the drop-down menu.

4. Click *Export* from the bottom right of the DDM window, enter a name for the exported file, and click *Save*. Click *OK* to acknowledge a successful export.

Note: After you complete an export **you will need to click *Close* to close the export panel before attempting a different export (see Figure 49).**

# E-7 Backing Up Mobile Device Data

An additional way to ensure that no testing data get lost is to perform a "device backup." Once data have been collected with the mobile device, you may back up the mobile device's data at any time.

To back up a mobile device's data, perform the following steps:

1. Turn on the mobile device and unlock the screen.
2. On the mobile device, launch DANA from the Application Tray. You should be at the Login screen.
3. On the mobile device, press / select *Menu*, select *Manage Device / Transfer Data* from the menu that appears on-screen.
4. Open the DANA Data Manager (DDM) and open the appropriate Administrator(s) (click *Manage Administrators*, then click *Open Administrator*, then select the Administrator Key Store file(s) and click *Open*.) Once all Administrators are open, close the DANA Administrator Manager window.
5. In the DDM, click *Manage Device / Download Data*. A window similar to that in **Figure 50** should appear on-screen.
6. In this DDM window, click *Next* at the bottom. The window should now appear as in **Figure 51**.
7. In this DDM window, click *Create Device Backup*, select the location on the data management PC to save the backup files, and click *Choose*. The DDM should then back up the mobile device's data to a new folder (using the mobile device's serial number as the name) in the specified location.
8. In the DDM, click *OK* to confirm a successful backup.

Note: The encrypted connection between the mobile device and the DDM / data management PC will terminate once the mobile device backup is completed.

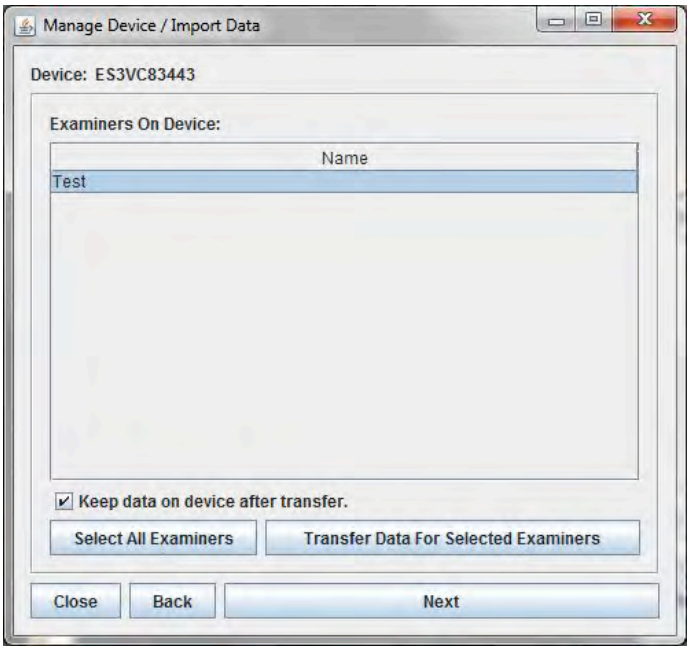



Figure 50

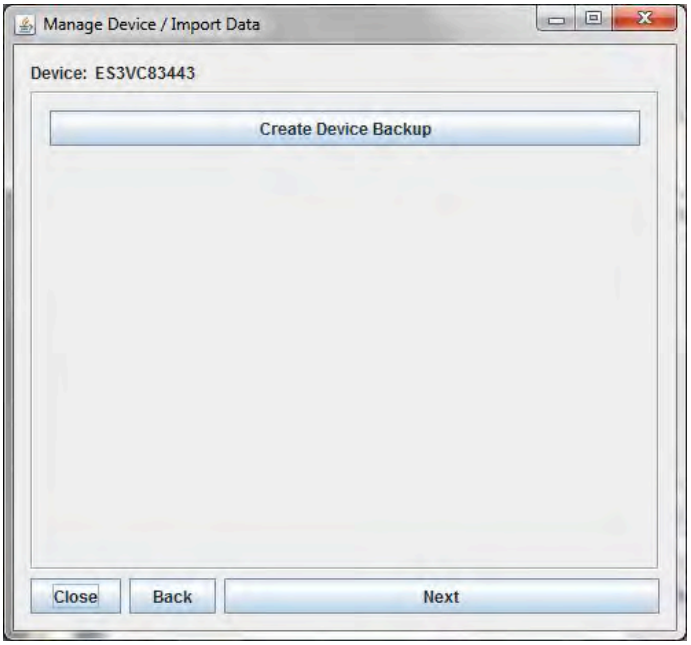



Figure 51

# E-8 Powering OFF the Mobile Device

To power OFF the mobile device press and hold the power button until the *Phone Options* screen displays (**Figure 52a**). Then select the *Power Off* option, and confirm the action by selecting *OK* in the subsequent *Power off* window (**Figure 52b**).

**Remember!** Pressing only the power button does not turn off the mobile device. The screen will go blank and result in a stand by state, continuing to drain the battery.

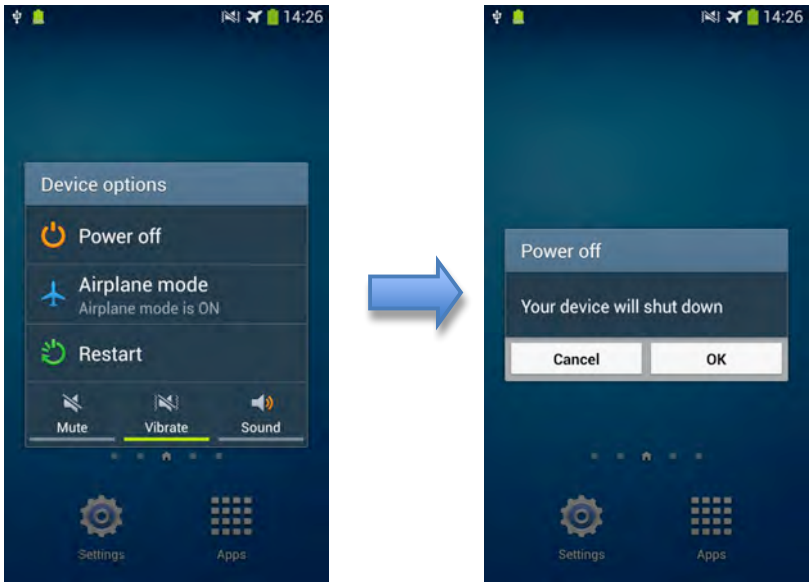



Figure 52a Figure 52b

# E-9 Uninstalling DANA

Note: Uninstalling DANA will erase all data on the mobile computer!

1. In the Settings menu, go to the Application manager section.
2. Select DANA from the list.
3. Select *Uninstall* and then *OK* to confirm.

# E-10 Uninstalling the DANA Data Manager

1. Uninstall the DANA Data Manager the same way other Windows programs are uninstalled via the Control Panel.

# Section F – Explanation of Assessment Measures

## F-1 Details of DANA Test Batteries

DANA's default configuration is comprised of three test batteries, each consisting of multiple tests. The table below lists these three test batteries and the tests that make up each battery (in the order in which they occur).

Table 2

| DANA Rapid (5 minutes) | DANA Brief (15 minutes) | DANA Standard (45 minutes) |
|---|---|---|
| Simple Reaction Time | Simple Reaction Time | Simple Reaction Time |
| Procedural Reaction Time | Code Substitution (Learning) | Code Substitution (Learning) |
| Go/No-Go | Procedural Reaction Time | Procedural Reaction Time |
| *Optional*: Combat MACE interview (additional 10 min.) | Spatial Processing | Spatial Processing |
| | Go/No-Go | Go/No-Go |
| | Code Substitution (Recall) | Code Substitution (Recall) |
| | Simple Reaction Time | Matching to Sample |
| | Patient Health Questionnaire (PHQ-8) | Simple Reaction Time |
| | Primary Care-PTSD Screen (PC-PTSD) | Combat Exposure Scale (CES) |
| | Insomnia Severity Index (ISI) | Patient Health Questionnaire (PHQ-8) |
| | | Pittsburgh Sleep Quality Index (PSQI) |
| | | PTSD Check List-Military Version (PCL-m) |
| | | Deployment Stress Inventory (DSI) |

# F-2 Details of DANA Assessments

The individual DANA assessments (tests) are described below. The assessments are grouped by category – Cognitive Tests and Psychological Tests.

Depending on the type of mobile device you are using to run DANA, the graphics in the figures below may appear differently on screen.

## F-2-1 Cognitive Tests

Please see relevant references in the *References* section.

### Simple Reaction Time

Structure: This task measures pure reaction time and cognitive processing time. The subject will tap on the location of the yellow asterisk symbol as quickly as possible each time it appears. This task will be repeated until testing is completed.

DANA Purpose: This test targets sensory motor functioning.

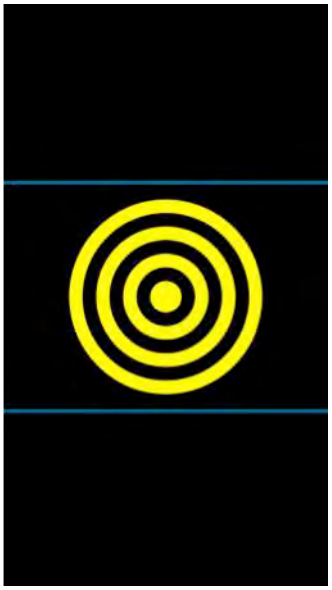


Figure 53

### Code Substitution (Learning)

Structure: Subjects refer to a set of 9 symbol-digit pairs that are shown in a "key" across the upper portion of the screen. A sequence of single symbol-digit pairs is shown below the key, and the subject indicates whether or not the single pair matches one in the key.

DANA Purpose: Assesses executive capacity, and immediate memory and attention.

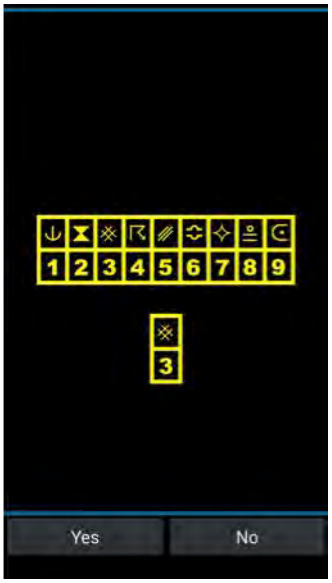



Figure 54

## Code Substitution (Recall)

Structure: After a delay, symbol-digit pairs are presented without the key. The subject indicates whether or not the pairing was included in the key that was presented in the earlier Code Substitution learning section.

DANA Purpose: Assesses executive capacity and short-term memory.

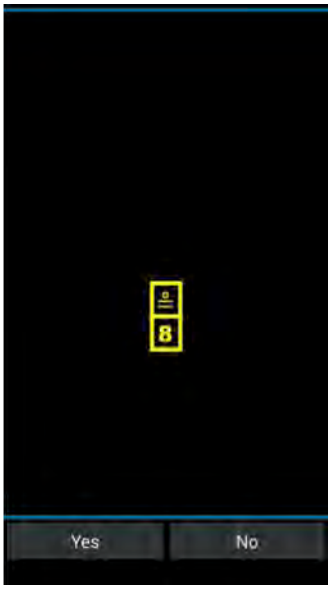



Figure 55

## Procedural Reaction Time

Structure: The screen will display one of four numbers at a time allowing for 3 seconds before displaying the next number. The Subject will be asked to differentiate whether the number that appears on the screen is *2 or 3* or *4 or 5*.

DANA Purpose: This test targets executive functioning with decision-making capabilities.


Figure 56

## Spatial Processing

Structure: Pairs of four-bar histograms are presented simultaneously on the screen, one rotated 90° from the other. The subject determines if the two histograms are same or different.

DANA Purpose: Assesses executive capacity and spatial manipulation.


Figure 57

## Go/No-Go

Structure: This is a reaction time, forced choice task relevant to warfighters. A house is presented on the screen with several windows. Either a *friend* (green) or *foe* (white) appears in a window. The respondent must push a button only when a *foe* appears.

DANA Purpose: The test assesses speed and accuracy of targets, omissions, and commissions in order to derive a sensitivity metric, as found in continuous performance tasks.

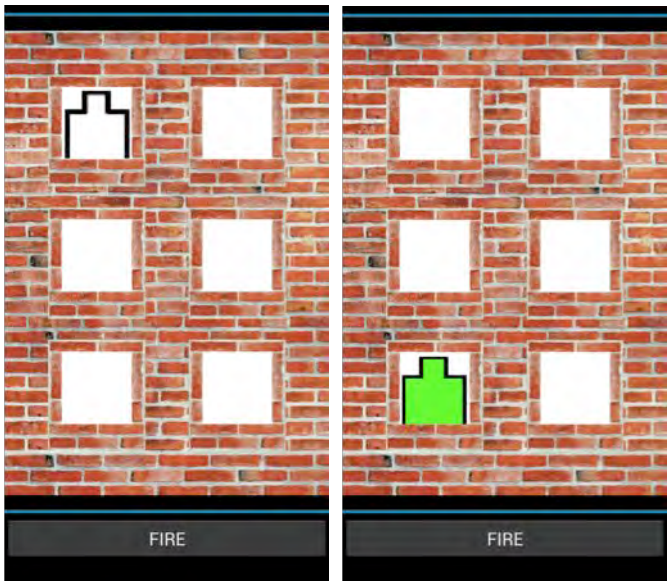



Figure 58

### Matching to Sample

Structure: A single 4x4 checkerboard pattern is presented on the screen for a brief study period. It then disappears for 5 seconds, after which two patterns are presented side-by-side. The subject indicates which of these two patterns matches the first.

DANA Purpose: This test is a measure of short-term memory, attention, and visual-spatial discrimination.

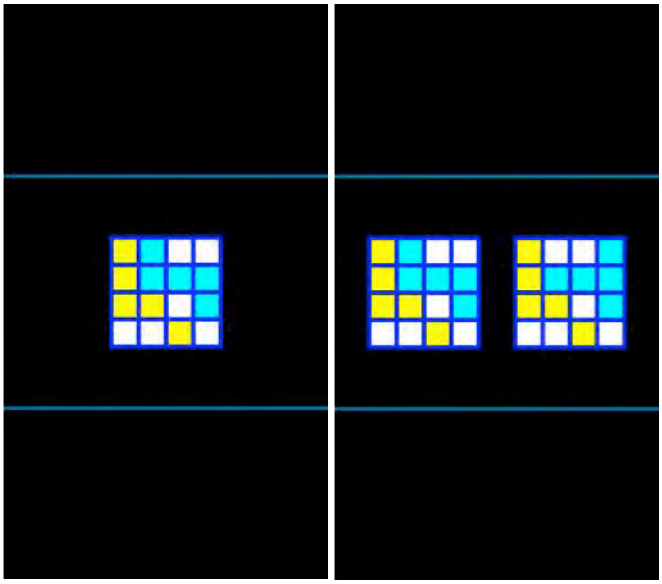


Figure 59

## F-2-2 Psychological Tests

### Combat Exposure Scale (CES)

Author / Source: Keane, T., Fairbank, J., Caddell, J., Zimering, R., Taylor, K., & Mora, C. (1989). *Clinical evaluation of a measure to assess combat exposure*. Psychological Assessment, 1, 53-55.

Structure: A 7-item self-report measure that assesses wartime stressors experienced by Service Members. The total CES score (ranging from 0 to 41) is calculated by using a sum of weighted scores, which can be classified into 1 of 5 categories of combat exposure ranging from “light” to “heavy.”

DANA Purpose: This scale rates cumulative combat exposure and is highly predictive of PTSD, pain and injury, TBI, depression, and other behavioral sequellae.

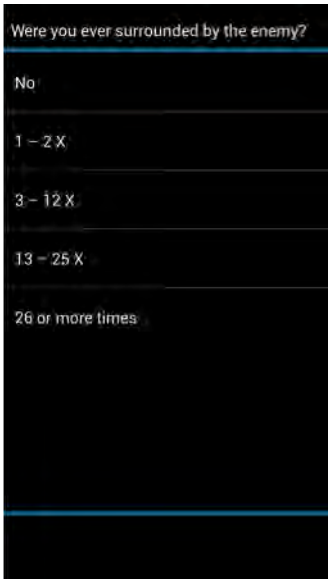



Figure 60

## Patient Health Questionnaire (PHQ-8)

Author / Source: Kroenke K, Spitzer RL. The PHQ-9: A new depression and diagnostic severity measure. Psychiatric Annals 2002; 32: 509-521.

Structure: A 9-item Depression Scale assessing symptom severity and diagnostic criteria for major depressive disorder. For research purposes, item #10 (concerning suicide) was not included, yet research indicates that the scoring, reliability, and clinical validity are almost identical.

DANA Purpose: A score of 0-9 is likely to have no depression, 10-14 mild depression, 15-19 moderate depression, and 20+ severe depression.

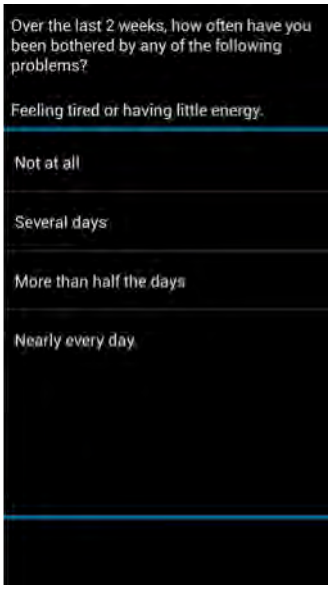



Figure 61

## Primary Care PTSD Screen (PC-PTSD)

Author / Source: Prins, A., Ouimette, P., Kimerling, R., Cameron, R.P., Hugelshafer, D.S., Show-Hegwer, J., Thrailkill, A., Gusman, F.D., Sheikh, J.I. (2003). The primary care PTSD screen (PC-PTSD): Development and operating characteristics. *Primary Care Psychiatry, 9,* 9-14.

Structure: Four screening questions designed for use in clinical settings to screen for PTSD, with 3-4 endorsed items suggestive of likely PTSD.

DANA Purpose: Questions assess hyper-arousal, re-experiencing, and avoidance for PTSD Screening. This test is more sensitive than specific, but correlates highly with the PCL.

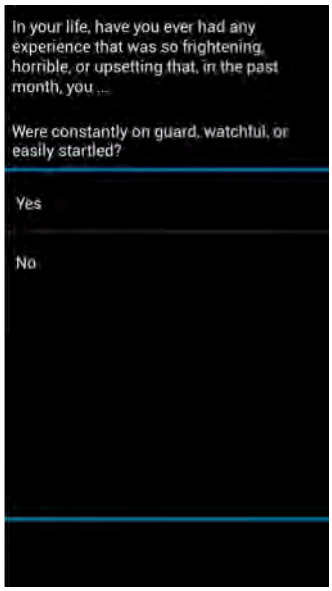



Figure 62

## Insomnia Severity Index (ISI)

Author / Source: Morin, C., Vallières, A., Guay, V., Ivers, H., Savard, J., Me'rette, C., Bastien, C., Bailargeon, L. (2009). Cognitive Behavioral Therapy, singly and combined with medication for persistent insomnia: A randomized controlled trial. *JAMA, 301* (19), 2005 – 2015.

Structure: A 5-item scale evaluating perceived insomnia severity and sleep habits. Each item is rated on a five-point scale (0–4).

DANA Purpose: The total score ranges from 0 to 28 and higher scores indicate more severe insomnia. A cutoff score of 10 has been shown to indicate insomnia.

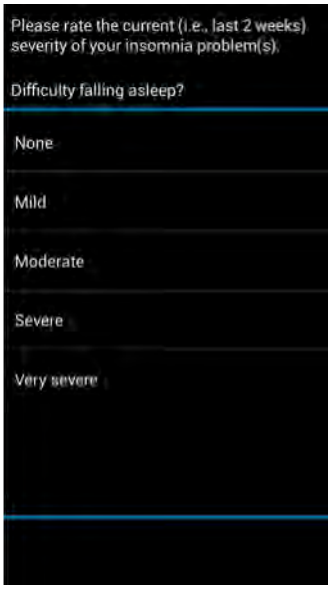



Figure 63

## Pittsburgh Sleep Quality Index (PSQI)

Author / Source: Buysse,D.J., Reynolds,C.F., Monk,T.H., Berman,S.R., & Kupfer,D.J. (1989). The Pittsburgh Sleep Quality Index (PSQI): A new instrument for psychiatric research and practice. Psychiatry Research, 28(2), 193-213.

Structure: 19 self-rated items and 5 partner-rated items, which measure sleep quality during the previous month. This scale differentiates "good" from "poor" sleepers based on seven areas: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction over the last month.

DANA Purpose: This scale is the most widely utilized sensitive and specific self-report measure for insomnia. A score above 5 indicates a "poor" sleeper.


Figure 64

## PTSD Checklist – Military Version (PCL-m)

Author / Source: Weathers, F., Litz, B., Herman, D., Huska, J., & Keane, T. (October 1993). The PTSD Checklist (PCL): Reliability, Validity, and Diagnostic Utility. Paper presented at the Annual Convention of the International Society for Traumatic Stress Studies, San Antonio, TX.

Structure: A 17-item scale assessing symptoms in response to stressful military experiences. This scale assesses: Re-Experiencing, Avoidance / Numbing, and Hyperarousal.

DANA Purpose: Higher scores indicate increased PTSD symptomatology. In a military population, scores >50 are likely to have PTSD. More specifically, scores >44 with 1 Re-experiencing, 3 avoidance/numbing, and 2 Hyperarousal enorsed as at least "most of the time" are more specific for PTSD and correlate very highly with the Clinician Administered PTSD Scale (CAPS).

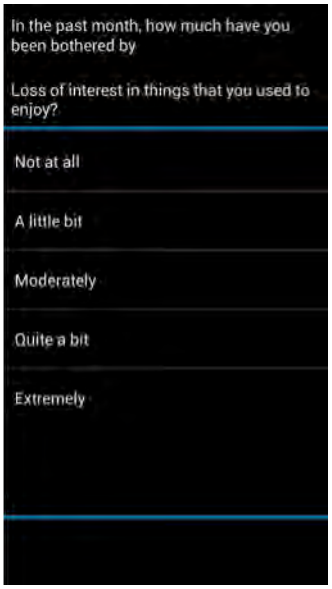



Figure 65

## Deployment Stress Inventory (DSI)

Author / Source: Reeves, Bleiberg, Spira, Russell, Obrecht, Kelly, et al.
**The authors of this scale are involved in the DANA project.**

Structure: This test is a 28-item experimental scale with 5 domains, including anger, pain, post-concussive symptoms, depression/suicidal ideation, and exhaustion.

DANA Purpose: This experimental measure is intended to be used as a broad psychological screening tool sensitive to combat-related distress.


Figure 66

## Demographics Survey

Author / Source: Spira
**The authors of this survey are involved in the DANA project.**

Structure: This is an 11-item survey that asks the subject about basic demographics (e.g., age, gender, rank) and concussion history information.

DANA Purpose: Age, gender, and concussion history information.

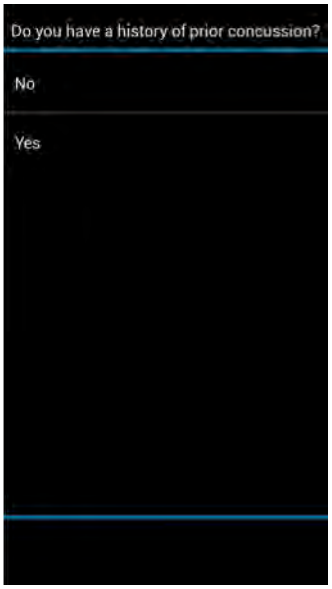



Figure 67

# Section G – Troubleshooting Guide

## DANA will not successfully launch on my mobile device.

- Turn off your mobile device, turn it back on, and try to launch DANA again.
- Uninstall DANA, reinstall DANA, and then try to launch DANA again.

  Note: Uninstalling DANA will permanently remove any data, Examiners, or Administrators from your mobile device.

## My mobile device is not recognized by or will not successfully "connect" to the DANA Data Manager.

- Make sure that you are using compatible versions of DANA, the DANA Data Manager, and Android:

  Note: Some incompatibility exists due to the different ways Android 4.3 and Android 4.2.2 (and prior) handle data encryption. And since DANA and the DANA Data Manager form an encrypted connection prior to performing data transfers or setting up DANA (adding Administrators and test battery packages), this difference in Android's encryption protocol affects the encrypted connection DANA makes with the DANA Data Manager. In practical terms, this means that:
  - The DANA Data Manager v1.1.10 cannot make an encrypted connection with DANA v1.5.2 (or prior), and
  - The DANA Data Manager v1.1.9 (or prior) cannot make an encrypted connection with DANA v1.5.3.

  - To check the version of DANA, launch DANA from the apps tray on the mobile computer. The version of DANA installed (e.g., *Version 1.5.3*) should be present just below the DANA logo on the login screen.
  - To check the version of the DANA Data Manager (DDM), launch the DDM on your PC. The version of the DDM installed (e.g., *Version 1.1.10*) should be present just below the DANA logo on the main screen.
  - To check the version of Android running on your mobile computer, go into the Settings menu from the apps tray on the mobile computer. (Note: The layout and submenu names in the Settings menu may vary depending on the type of mobile computer and version of Android installed.) Select the submenu called *About device* (the name of this submenu may be slightly different). In the screen that appears, the Android version number should be listed.

  The following table describes the compatibility among versions of DANA, the DANA Data Manager, and Android.

| | **DANA Data Manager v1.1.10** | **DANA Data Manager v1.1.9** | **Android v4.3+** | **Android v4.2.2 (and prior)** |
|---|---|---|---|---|
| **DANA v1.5.3** | ● | Can open datasets; Cannot create encrypted connection | ● | ● |
| **DANA v1.5.2 (and prior)** | Can open datasets; Cannot create encrypted connection | ● | Incompatible | ● |

Levels of compatibility between DANA and the DANA Data Manager (DDM):
  - Fully compatible (green circle) means that the DDM can perform all functions (transfer data, set up DANA, open datasets, etc.).
  - "Somewhat" compatible means that the DDM can open already-transferred datasets (and subsequently export their data), but that the DDM cannot transfer data or fully set up DANA on a mobile computer.

- Make sure that the mobile device is securely connected to the PC with a functional USB cable:
  - Unplug the mobile device from the PC and then plug it back in.
  - Alternatively, try using a different USB cable.

- Make sure USB Debugging is enabled in the Settings menu (see *Developer Options* in **Section D-2**).

- Make sure that your mobile device's screen timeout setting is adjusted so that its screen does not timeout before a connection is made with the DDM:
  - To check or adjust this setting go to *Settings* > *Display* > *Timeout*.

- Make sure that your mobile device's driver is installed on the PC:
  - See **Section C-2 – Step 3**.
  - Alternatively, visit the website of the mobile device's manufacturer. Typically, in the *Support* section of the website, file downloads are available (including driver files) for their various products. Download these driver files and follow any install instructions.

- Make sure that the correct Administrator is open in the DANA Data Manager (DDM):

  Note: The Administrator file open in the DDM must match the Administrator on the mobile device in order to initiate a secure connection between mobile device and DDM.)
  - See **Section C – Step 3** for how to add an Administrator to the mobile device.
  - Alternatively:
    - Launch the DANA Data Manager (DDM), click *Manage Administrators*, and open the appropriate Administrator(s). Expand the DDM window so that you can see the entire *Signature*.
    - Launch DANA on the mobile device, log in, press the Menu button, select *Edit Examiner*, then select *View administrators with access to this examiner.* The Administrators on this mobile device (and their signatures) will then be listed.
    - Compare the signature(s) of the Administrator(s) open in the DDM to that / those of the Administrator(s) on the mobile device.
      - If none of the signatures match, this will impede any secure connection between the mobile device and DDM. You will need to open the correct Administrator in the DDM and retry the connection or create a new Administrator and add it to the mobile device.

        Note: If you have already created an Examiner on the mobile device, you will not be able to add any more Administrators to the device unless you uninstall and then reinstall DANA. Uninstalling DANA will erase all data from the mobile device.
      - If at least one pair of signatures matches, this is not the cause of your secure connection problem.

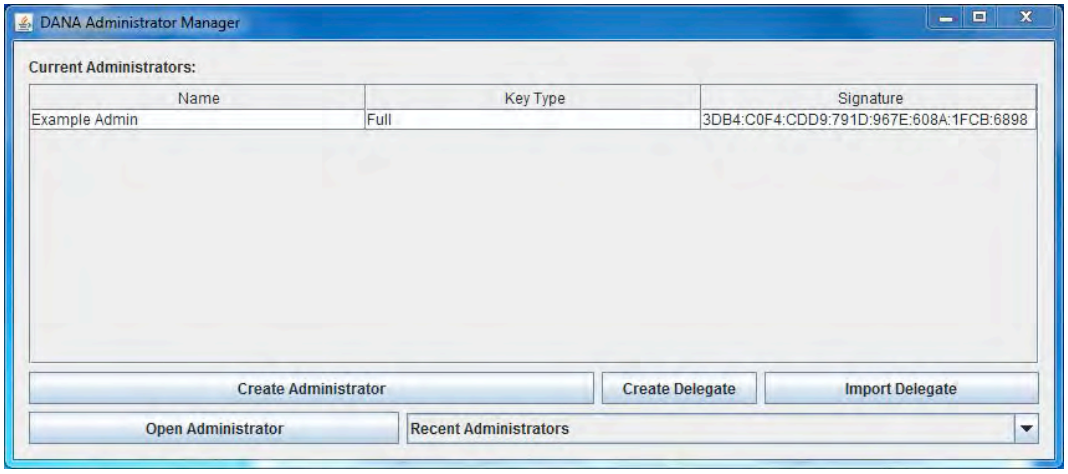



Figure 68

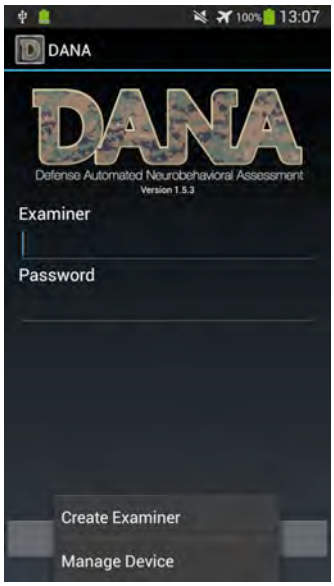



Figure 69a

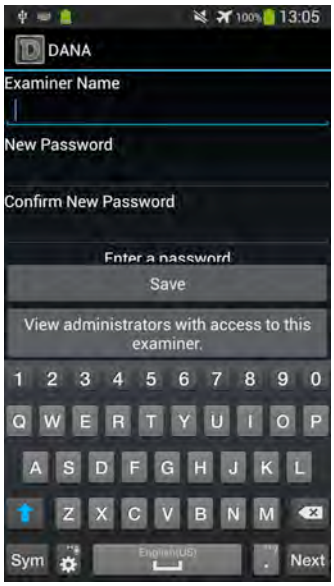



Figure 69b

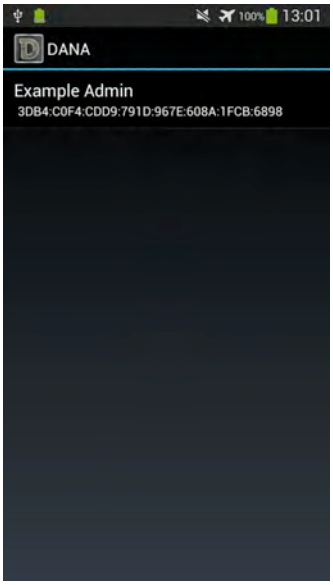



Figure 69e

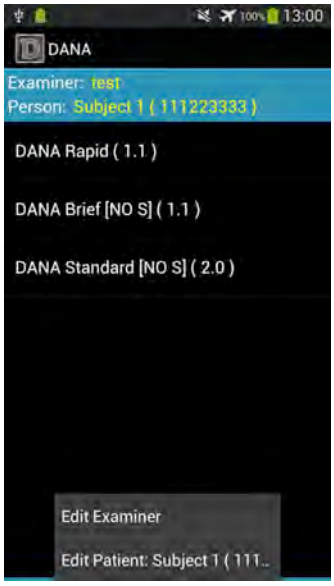



Figure 69c

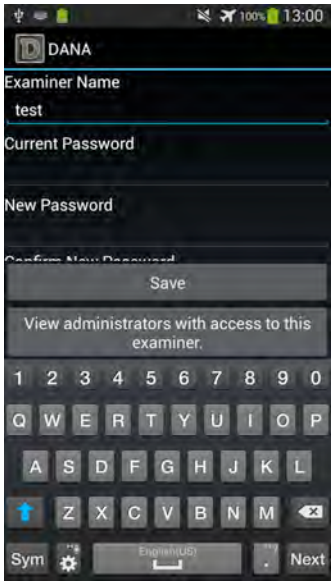



Figure 69c

- Make sure that your Android SDK packages are up to date.
    - Ensure your PC has an Internet connection, launch the Android SDK Manager (via the Start Menu), and check the "Status" of the packages in the Tools folder.
        - If the status is "Installed," no action is required.
        - If the status is "Not installed" or "Update available," select these packages and then click *Install __ packages...* or *Update __ packages...* at the bottom right of the window.
        - See **Section C-2 – Step 6** for additional help.
- Uninstall Java from your PC and then reinstall it.
    - Uninstall Java from your PC via the Control Panel.
    - Complete Steps 4 & 5 in Section B.
    - Restart the DANA Data Manager (if it is open) and then retry making an encrypted connection between your device and the DANA Data Manager.

## The DANA Data Manager will not open a dataset or an Administrator.

- You may have entered the wrong password in the first attempt. The DANA Data Manager will not allow you to open a dataset or Administrator after an unsuccessful attempt unless you restart the program.
    - Close the DANA Data Manager, reopen it, and retry opening the dataset or Administrator.

## The DANA Data Manager (DDM) application will not open.

- If your PC is running Windows XP, see **Section C-2 – Step 2** and follow the instructions listed there.

- Repeat the steps listed in **Section C-2 – Step 5**. Then try again to open the DDM.

- If your PC is running Mac OS X, the default application security setting may be causing the problem. To solve the problem:
    - Open the Security & Privacy settings menu in your System Preferences ( > *System Preferences* > *Security & Privacy*). In this menu, change the *Allow apps downloaded from:* setting to *Anywhere*. Then, try opening the DANA Data Manager again.

- If the steps above do not work, uninstall and then reinstall the DDM and then try to open the DDM application. See **Section E-10** for uninstall instructions and **Section C-2 – Step 8** for install instructions.

## My mobile device is unresponsive to button presses or screen selections.

- Ensure that the mobile device's battery is charged.
- Turn the mobile device OFF, then turn it back on, then retry the application.
- Turn the mobile device OFF, take out the battery, and put it back in (you may have to remove battery cover). Then power the mobile device back ON and retry the application.

Note 1: Consult your mobile device's user manual for instructions on how to remove the battery safely.

Note 2: Taking out the battery may reset the date and time on your mobile device.

## I finished setting up my mobile device with the DANA Data Manager, but I need to add one or more additional test battery packages.

Note: You can add additional test battery packages to a mobile device at any time after it has been initially set up.

- If you have closed the Manage Device / Import Data window in the DANA Data Manager (i.e., you have terminated the encrypted connection between the mobile device and the PC), you must reestablish that encrypted connection first:
    - Make sure that (a) the mobile device is on and plugged into your PC with its USB cable and (b) the DANA Data Manager is running on your PC.
    - Launch DANA, press the Menu button, and select *Manage Device* from the menu that appears.
    - In the DANA Data Manager, click *Manage Device / Download Data*.

- If you have not closed the Manage Device / Import Data window in the DANA Data Manager, you can simply go backward and then add the battery packages:
    - In the Manage Device / Import Data window of the DANA Data Manager, click *Back* until you arrive at the screen listing the test batteries on the device.
    - Once at that screen, click *Load Test Battery Package*, navigate to the test battery package file you want to add, select the file, and click *Open*.
    - Repeat this process as many times as necessary until all of the desired test battery packages have been loaded.
    - At this point, you may simply close the Manage Device / Import Data window and begin using DANA.

## I finished setting up my mobile device with the DANA Data Manager, but I need to add one or more additional Administrators.

Note: Unfortunately, at this time, once you have created and added an Examiner to your mobile device, you may not add any additional Administrators.

- To add any additional Administrators after an Examiner has been added to a mobile device, you must uninstall and then reinstall DANA first:

    Note: Uninstalling DANA will permanently remove any data, Examiners, or Administrators from your mobile device.

    - Make sure that (a) the mobile device is on and plugged into your PC with its USB cable and (b) the DANA Data Manager is running on your PC.
    - Launch DANA, press the Menu button, and select *Manage Device* from the menu that appears.
    - In the DANA Data Manager, click *Manage Device / Download Data*.
    - Add any Administrators you wish to the mobile device.
    - Complete the mobile device setup process (create an Examiner, add test battery packages).

## A test battery was aborted for some reason (force close error, Home button press, screen put to sleep, etc.) during a screening.

- Resume or discard the screening via the *Resume Aborted Screening* feature (see **Section E-2**).

## The DANA Data Manager will not open and the following error appears on-screen (in Windows):

***This application has failed to start because MSVCR100.dll was not found. Re-installing the application may fix this problem.***

- Determine if the version of Windows XP running on your data management PC is 32-bit (x86) or 64-bit (x64):
    - From the Start Menu, select *Run*.
    - Type *msinfo32* and click *OK*.
    - A Window containing your system's information should appear. In that window, look for *System Summary* and look for *System Type*. This should tell you if your system is x64 or x86.
- Download the correct (x86 or x64) and most recent Microsoft Visual C++ Redistributable Package from either:
    - x86: http://www.microsoft.com/download/en/details.aspx?id=5555
    - x64: http://www.microsoft.com/download/en/details.aspx?id=14632

- Launch the file you just downloaded and complete the installation procedure that follows, accepting all default configurations.

# Appendix A – Data Export Options

Once test data are collected on the mobile device and then transferred to a PC (in DANABase format), they can be exported into a range of additional, more usable formats for data analysis or custom report generation. The available export options are summarized in the following table.

Table 3

| Export Option | File Format | Files Generated | Cognitive Test Data Included? | Psycho-logical Test Data Included? | Trial-by-Trial Data Included? | Notes |
|---|---|---|---|---|---|---|
| XML | XML | (See Notes) | Yes | Yes | Yes | One file per test per Subject |
| Full Report | HTML | (See Notes) | Yes | Yes | Yes | One file per test per Subject |
| PDF Report | PDF | (See Notes) | Yes | Yes | Yes | One file per test per Subject |
| Test Statistics | CSV | 3-7 | Yes | No | No | One file per Cognitive test |
| Test Responses | CSV | 3-7 | Yes | No | Yes | One file per Cognitive test |
| Single Row per Subject | CSV | 1 | Yes | Yes | No | Psychological data includes only scores, not responses |
| Demographics | CSV | 1 | n/a | n/a | Yes (See Notes) | Responses to Demographics Survey |
| Extended Format – User UUID | CSV | 7-25 | Yes | Yes | Yes | Two files per test / survey, plus 1-3 files with overall screening information. |
| Extended Format | CSV | 4-19 | Yes | Yes | Yes | 1-2 files per test / survey, plus three files with overall screening information |
| Finger Tapping Test Export | CSV | 2 | Yes | n/a | n/a | Responses to Finger Tapping Test |
| Raw Balance Data | CSV | 5 per stance | n/a | n/a | n/a | Raw sensor data collected during the Balance test |
| Raw Data | CSV | 13-22 | Yes | Yes | Yes | |

These options are described in more detail in the remainder of this appendix.

## 1. Export to XML

Single file per input export format. Data is the input result in XML format. Mainly useful for development of custom XSLT for reports.

## 2. Export Full Report

Single file per input export format. Exports the full report HTML content.

## 3. Export to PDF Report

Single file per input export format. Creates a PDF report of the input result.

## 4. Export: Test Statistics

Multi-file export format. A single file is created for each test type in the result input set. Each test instance from the result input set creates a single line in the appropriate files. Created files are named after the test types with a CSV extension. For example, DANA Rapid contains the following tests:

Reaction TIme, Procedural Reaction Time, Go No Go.

The export will produce the files:

Reaction Time.csv, Procedural Reaction Time.csv, and Go No Go.csv

Each file contains computed statistics for the specific tests in the input result set. Note that this test does not export any information for survey tests. Each test type produces at least the following columns:

| Column Name | Description |
|---|---|
| ID | Subject ID |
| UUID | Subject UUID |
| Sex | Taken from demographics survey of subject, or blank |
| Age | Taken from demographics survey of subject, or blank |
| Education | Taken from demographics survey of subject, or blank |
| Rank | Taken from demographics survey of subject, or blank |
| Concussed | Taken from demographics survey of subject, or blank |
| Administration | Administration number |
| Date | Date test was started. |
| Time | Time test was started. |
| Location | Location information extracted from subject ID if available, or blank. |
| Subject Condition | blank |
| Device Condition | blank |
| Mean RT Correct Responses | |
| Median RT Correct Responses | |
| SD of Mean RT Correct | |
| Mean RT Incorrect Responses | |

| Column Name | Description |
|---|---|
| Median RT Incorrect Responses | |
| SD of RT Incorrect Responses | |
| Number impulsive Responses | |
| Number Lapsed Responses | |
| Percent Correct Responses | |
| Throughput | |
| Battery Type | Name of DANA battery |
| DANA Version | Version of DANA Used. |

Additionally, for the Matching To Sample test, the following columns are included.

| Column Name | Description |
|---|---|
| STD Mean RT Correct Responses | |
| STD Median RT Correct Responses | |
| STD SD of Mean RT Correct | |
| STD Mean RT Incorrect Responses | |
| STD Median RT Incorrect Responses | |
| STD Median RT Incorrect Responses | |
| STD SD of RT Incorrect Responses | |
| STD Number Impulsive Responses | |
| STD Number Lapsed Responses | |
| STD Percent Correct Responses | |
| MAL Mean RT Correct Responses | |
| MAL Median RT Correct Responses | |
| MAL SD of Mean RT Correct | |
| MAL Mean RT Incorrect Responses | |
| MAL Median RT Incorrect Responses | |

| Column Name | Description |
|---|---|
| MAL SD of RT Incorrect Responses | |
| MAL Number Impulsive Responses | |
| MAL Number Lapsed Responses | |
| MAL Percent Correct Responses | |

## 5. Export: Test Responses

This is a multi-file export format. A single file is created for each test type in the result input set. Each trial in each test instance from the result input set creates a single line in the output. Created files are named after the test types with a CSV extension.

For example, DANA Rapid contains the following tests:
Reaction TIme, Procedural Reaction Time, Go No Go.

The export of DANA Rapid data will therefore produce the files:
Reaction Time.csv, Procedural Reaction Time.csv, and Go No Go.csv

Each line in the output files represents a single trial in a test in the input result set. Each test type has several unique columns along with several generic columns. Survey tests are not exported in this format.

**General Columns:**

| Column Name | Description |
|---|---|
| ID | Subject ID |
| UUID | Subject UUID |
| Sex | Taken from demographics survey of subject, or blank |
| Age | Taken from demographics survey of subject, or blank |
| Education | Taken from demographics survey of subject, or blank |
| Rank | Taken from demographics survey of subject, or blank |
| Concussed | Taken from demographics survey of subject, or blank |
| Administration | Administration number |
| Date | Date test was started |
| Time | Time test was started |

| Column Name | Description |
|---|---|
| Location | Location information extracted from subject ID if available, or blank. |
| Subject Condition | blank |
| Device Condition | blank |
| Trial Number | The index of the current trial in the current test. The first trial is 1, and so on. |
| Response | Text response type |
| Response (Numeric) | Numeric response type |
| Response Time | |
| Intertrial Interval | |
| SOA | Always 0 |
| Custom Test Columns | See table below based on test type |
| Speed Rank | Speed rank is the index into the sorted ordering of the trials by response time. Lowest response time will have speed rank 1. In Go/No-Go tests, only Go trials are ranked. |
| Slow Rank | Same as speed rank, but rank 1 is the slowest trial |
| Battery Type | Name of DANA test battery |
| DANA Version | Version of DANA used |

**Custom Test Columns:**

Code Substitution:

| Column Name | Description |
|---|---|
| Is Recall | True if this is a recall trial. Recall trials do not show the code key above the stimulus. |
| Shown Symbol | Which symbol was shown |
| Shown Number | Which number was shown |
| Is Correct Pair | True if the show symbol and number match in the code key. |

Go / No-Go:

| Column Name | Description |
|---|---|
| Is Foe | True if a foe (Go) appeared in this trial |
| Target Window | Window in which the stimulus appeared |

Matching To Sample:

| Column Name | Description |
|---|---|
| Symbol Position | Position where the symbol was shown |
| Selected Symbol Changes | Number of changes from the stimulus in the selected symbol. 0 if the correct response was given. |
| Foils max changes | Maximum number of changes in the shown foils |
| Number of Foils | Number of foils shown |
| Is Malingering Trial | True if the malingering configuration was used to generate this trial |

Procedural Reaction Time:

| Column Name | Description |
|---|---|
| Stimulus | The number shown as the stimulus |

Spatial Processing:

| Column Name | Description |
|---|---|
| Stimulus Graph | Shown stimulus graph heights |
| Rotated Graph | Shown rotated graph heights |
| Rotation | CW (clockwise) or CCW (counter-clockwise) rotation |
| Is Identical Graph | True if the two graphs are the same |

## 6. Export Single Row Per Subject

This is a single-file export format. Each subject from the input result set generates a single line in the output CSV file. General information about each test result is included in the export.

**General columns:**

| Column Name | Description |
|---|---|
| ID | Subject ID |
| SITE | Testing site extracted from subject Id or blank |

Test columns are prefixed with the test name abbreviation, and the administration number (e.g., RT-1-Mean RT Correct).

**Columns for all cognitive tests:**

| Column Name | Description |
|---|---|
| Mean RT Correct | Mean correct response time |
| Median RT Correct | Median correct response time |
| % Correct | Percent of correct responses |

Each survey test additionally has a column name SCORE. PCL-M and DSI additionally have columns to report sub scores, and DSI and Demographics also has a column for each question and the response.

Note that this export has the potential to generate an extreme number of columns, all of which may not be imported correctly in some third party software.

# 7. Export: Demographics

This is a single-file export containing results of the Demographics Survey test only. This creates a single Demographics.csv file. Each input result containing a demographics survey creates a row in the CSV output.

**Columns created:**

| Column Name | Description |
|---|---|
| ID | Subject ID |
| Deployed | |
| Age | |
| Rank | |
| Sex | |
| Education | |
| Prior Concussion | |
| Most recent concussion | |
| Dazed | |
| Memory | |
| LOC 1m | Loss of consciousness for 1 minute or less |
| LOC greater than 1m | Loss of consciousness for more than 1 minute |
| Concussion Count | Number of reported concussions |

# 8. Export: Extended Format – User UUID

UUID = Universally Unique Identifier

**Files Output for DANA Rapid:**

- BatteryInfo.csv
- Go No Go-Stats.csv
- Go No Go.csv
- Procedural Reaction Time-Stats.csv
- Procedural Reaction Time.csv
- Reaction Time-Stats.csv
- Reaction Time.csv

**Files Output for DANA Brief:**

- BatteryInfo.csv
- Code Sub-Stats.csv

- Code Sub.csv
- Go No Go-Stats.csv
- Go No Go.csv
- ISI Survey-Survey.csv
- ISI Survey.csv
- PCPTSD Survey-Survey.csv
- PCPTSD Survey.csv
- PHQ-8-Survey.csv
- PHQ-8.csv
- Procedural Reaction Time-Stats.csv
- Procedural Reaction Time.csv
- Reaction Time-Stats.csv
- Reaction Time.csv
- Spatial Processing-Stats.csv
- Spatial Processing.csv

**Files Output for DANA Standard:**

- SurveyInfo.csv (only output if *Export Test Meta Data* check box is checked during export)
- Strings.csv (only output if *Export Test Meta Data* check box is checked during export)
- BatteryInfo.csv
- CES Survey-Survey.csv
- CES Survey.csv
- Code Sub-Stats.csv
- Code Sub.csv
- DSI [NO S]-Survey.csv
- DSI [NO S].csv
- Go No Go-Stats.csv
- Go No Go.csv
- Matching to Sample-Stats.csv
- Matching to Sample.csv
- PCLM Survey-Survey.csv
- PCLM Survey.csv
- PHQ-8-Survey.csv
- PHQ-8.csv
- Procedural Reaction Time-Stats.csv
- Procedural Reaction Time.csv
- PSQI Survey-Survey.csv
- PSQI Survey.csv
- Reaction Time-Stats.csv
- Reaction Time.csv
- Spatial Processing-Stats.csv
- Spatial Processing.csv

# 9. Export: Extended Format

This is a multi-file export containing almost complete battery result information. This is the most appropriate export format for capturing all DANA reported information in an external RDBMS. This export reports several classes of information: Meta information (Optional), Responses, Statistics, Survey, and Battery Information.

### Meta Information

This creates a CSV file titled SurveyInfo.csv containing details about the surveys in the input result set. This file enumerates all survey questions, as well as unique IDs for reference to the question text. The string version and question string ID form a unique pair that can be used to access the survey question. The following columns are included:

| Column Name | Description |
|---|---|
| Activity | Name of the survey test |
| Question # | Question number of the question in the survey. Starts at 0. |
| String Version | The question string version number |
| Question String ID | The question string ID number |
| Question String | Text of the question string |

A second file, Strings.csv, is created which details all possible fixed strings referenced in the input result set. This file contains the following columns:

| Column Name | Description |
|---|---|
| Version | The version integer, along with the ID – this forms a unique reference |
| String ID | The string ID, along with the version this forms a unique reference |
| Value | The string text |

### Response Information

For each test type in the input result set a file with the test name is created. Each row in the file represents a single test trial. These files are nearly identical to the Export: Test Responses files. The test specific columns mentioned in that format are included here, with the addition of columns for survey tests. The columns included are:

| Column Name | Description |
|---|---|
| ID | Subject ID |

| Column Name | Description |
|---|---|
| Result UUID | UUID for this battery result. |
| Date | Date of test |
| Time | Time of test |
| Trial Number | Trial number in test |
| Response | Text description of the response type |
| Response (Numeric) | Numeric response type. |
| Response Time | Response time in milliseconds |
| Intertrial Interval | Intertrial interval before this trial. |
| Test Round | Round of this test in the battery. |
| Custom Test Columns | See Export: Test Responses, and below. |
| Speed Rank | Speed rank is the index into the sorted ordering of the trials by response time. Lowest response time will have speed rank 1. In Go No Go tests, only Go trials are ranked. |
| Slow Rank | Same as speed rank, but for slowest trials. |
| Battery Type | Name of battery. |
| DANA Version | Version of DANA used. |

**Custom Test Columns**

This export includes all the custom columns mentioned in the “Test Responses” export. For survey tests it also includes the following columns:

| Column Name | Description |
|---|---|
| String Version | Question string version |
| Question ID | Question string ID |
| Answer | Answer Text |
| Answer ID | Answer string ID |
| Fill-in Value | Any special input value for this question. |
| Score | Score of this question if applicable. |

**Statistics Information**

A file for each test type in the input result set is created. The file is the test name with -Stats appended (e.g., Reaction Time-Stats.csv). Each test instance in the input result set creates a single column containing computed statistics for trials in that instance. Statistics information is not output for survey tests. The file contains the following columns:

| Column Name | Description |
|---|---|
| ID | Subject ID |
| Result UUID | UUID for this battery result. |
| Date | Date this test was started. |
| Time | Time this test was started. |
| Test Round | Round of this test in the battery. |
| Mean RT Correct Responses | |
| Median RT Correct Responses | |
| SD of Mean RT Correct | |
| Mean RT Incorrect Responses | |
| Median RT Incorrect Responses | |
| SD of RT Incorrect Responses | |
| Number Correct | |
| Percent Correct | |
| Number Incorrect | |
| Percent Incorrect | |
| Number Impulsive | |
| Percent Impulsive | |
| Number Lapsed | |
| Percent Lapsed | |
| Mean RT | |
| Median RT | |
| SD of RT | |

| Column Name | Description |
|---|---|
| Time in Test | This may not be correct for Matching To Sample. |
| Throughput | |
| Battery Type | Name of the battery |
| DANA Version | Version of DANA used |

Additionally, the following columns are created for the Matching To Sample test:

| Column Name | Description |
|---|---|
| STD Mean RT Correct Responses | |
| STD Median RT Correct Responses | |
| STD SD of Mean RT Correct | |
| STD Mean RT Incorrect Responses | |
| STD Median RT Incorrect Responses | |
| STD Median RT Incorrect Responses | |
| STD SD of RT Incorrect Responses | |
| STD Number Impulsive Responses | |
| STD Number Lapsed Responses | |
| STD Percent Correct Responses | |
| MAL Mean RT Correct Responses | |
| MAL Median RT Correct Responses | |
| MAL SD of Mean RT Correct | |
| MAL Mean RT Incorrect Responses | |
| MAL Median RT Incorrect Responses | |
| MAL SD of RT Incorrect Responses | |
| MAL Number Impulsive Responses | |
| MAL Number Lapsed Responses | |
| MAL Percent Correct Responses | |

**Survey Information**

For each survey type in the input result set, a file is created with the survey name and -Survey appended (e.g., PCPTSD Survey-Survey.csv). This file contains information about the survey score and any generated flags and sub-scales. These files contain the following columns:

| Column Name | Description |
|---|---|
| ID | Subject ID |
| Result UUID | UUID for this battery result. |
| Date | Date this test was started. |
| Time | Time this test was started. |
| Score | Computed score for this survey. |
| Range | Functional range for this survey result. (Red, Yellow, Green) |
| Notes | Any additional information generated by the survey scorer. |
| Red Flags | Any generated red flag information. |

**Battery Information**

The file BatteryInfo.csv contains information about each input result in the input result set. This file contains the following columns:

| Column Name | Description |
|---|---|
| ID | Subject ID |
| Result UUID | UUID for this battery result. |
| Date | Date this battery was started |
| Time | Time this battery was started |
| End Date | Date this battery was finished |
| End Time | Time this battery was finished |
| Elapsed ms | Time spent in this battery in milliseconds |
| Device Serial Number | Serial number of the Android device used. |
| Starting Battery level | Percentage of charge of the physical device battery when the test battery was started. |
| Ending Battery level | Percentage of charge of the physical device battery when the test battery was finished. |

| Column Name | Description |
|---|---|
| Battery Name | Test Battery name |
| Battery Sequence | A colon-delimited listing of the sequence of tests within the test battery. Each section is the abbreviated test name. |

## 10. Finger Tapping Test Export

This is an export specifically designed for handling Finger Tapping Test data. This option should only be used to export Finger Tapping Test data.

Files Output:
- Finger Tapping Test – Details.csv
- Finger Tapping Test – Stats.csv

## 11. Raw Balance Data

This is an export specifically designed for handling Balance test data. This option should only be used to export Balance test data.

This export outputs five CSV files for each stance that is performed: one for each of three sensors plus one tabulating all sensor data and one with overall sensor information.

Data from the following sensors are exported:
- Rotation vector sensor
- Magnetic field sensor
- Gravity sensor

## 12. Raw Data

Files Output for DANA Rapid:
- Battery Config.csv
- Battery Result - Results.csv
- Battery Result.csv
- Device Configuration.csv
- Go No Go Trial Report.csv
- Patient.csv
- Procedural Reaction Time Config.csv
- Reaction Time Config.csv
- String Blocks.csv
- Test Config.csv
- Test Report.csv
- Trial Report.csv
- Trial Test Report.csv

Files Output for DANA Brief:
- Battery Config.CSV

- Battery Result – Results.CSV
- Battery Result.CSV
- Code Sub Config.CSV
- Code Sub Trial Report.CSV
- Code Sub Trial Test Report.CSV
- Device Configuration.CSV
- Go No Go Trial Report.CSV
- Patient.CSV
- Procedural Reaction Time Config.CSV
- Reaction Time Config.CSV
- Spatial Processing Trial Report.CSV
- String Blocks.CSV
- Survey Question Report.CSV
- SurveyTestReport – Red Flags.CSV
- SurveyTestReport – Survey Results.CSV
- Test Config.CSV
- Test Report.CSV
- Trial Report.CSV
- Trial Test Report.CSV

Files Output for DANA Standard:

- Battery Config.CSV
- Battery Result – Results.CSV
- Battery Result.CSV
- Code Sub Config.CSV
- Code Sub Trial Report.CSV
- Code Sub Trial Test Report.CSV
- Device Configuration.CSV
- Go No Go Trial Report.CSV
- Matching to Sample Config.CSV
- Matching to Sample Trial Report.CSV
- Patient.CSV
- Procedural Reaction Time Config.CSV
- Reaction Time Config.CSV
- Spatial Processing Trial Report.CSV
- String Blocks.CSV
- Survey Question Report.CSV
- SurveyTestReport – Red Flags.CSV
- SurveyTestReport – Survey Results.CSV
- Test Config.CSV
- Test Report.CSV
- Trial Report.CSV
- Trial Test Report.CSV

# Appendix B – Navigating Android Operating System

The following is a brief introduction to navigating the Android operating system, DANA's native environment. More detail on using DANA in Android is provided in later sections of this user manual. Since manufacturers tailor Android in different ways to run on different devices, the screenshots and instructions in this section might be slightly different than what appears on your mobile device, but the basic layout and content should be similar.

## Home Screen

The main screen in Android is called the Home screen (**Figure 70a**). Pressing the Home button / icon on an Android mobile device will bring the user to this screen. From this screen, the user can launch various applications and access various menus. Two important menus accessed via the Home screen are the:

1) Home Quick Menu (**Figure 70b**)
   **To Access this Menu: Press / select the Menu button / icon on the device.
   a. Frequently used operations can be accessed via this menu.
   Note: Not all mobile devices may offer this feature.

2) Application Tray (**Figure 70c**)
   **To Access this Menu: Select and slide upward the grey menu handle at the bottom of the Home screen.
   a. All installed applications (e.g., DANA) can be accessed via this menu.
   b. Primary menus (e.g., Settings menu) can be accessed via this menu.
   Note: On a tablet computer, you may have to select an *Apps* icon from the Home screen to access the Application Tray. See the *DANA Mobile Device* section above.

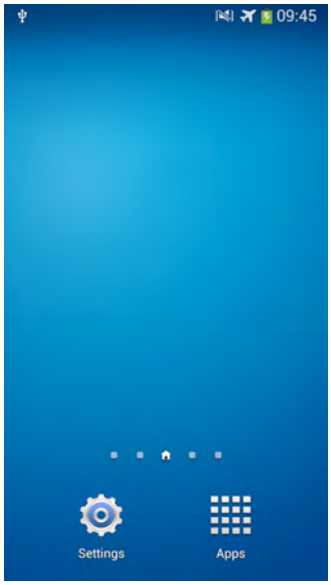


Figure 70a

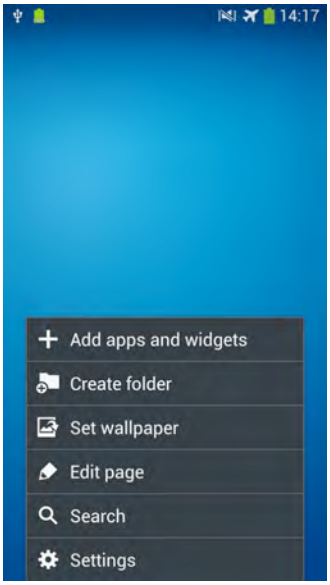


Figure 70b

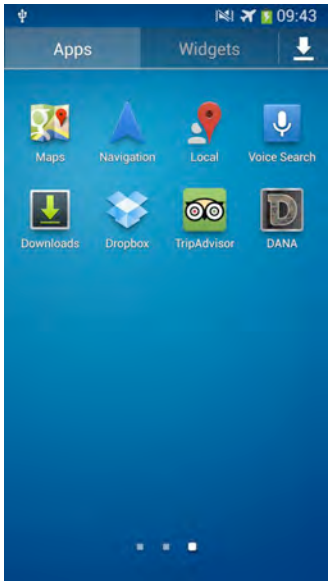


Figure 70c

## Settings Menu

All settings for the mobile device can be accessed via the *Settings* menu (**Figure 71**). From this menu, the user can turn Wi-Fi on or off (*Wireless & networks*), manage applications (*Applications*), adjust the date and time (*Date & time*), or adjust sound levels (*Sound & display*).

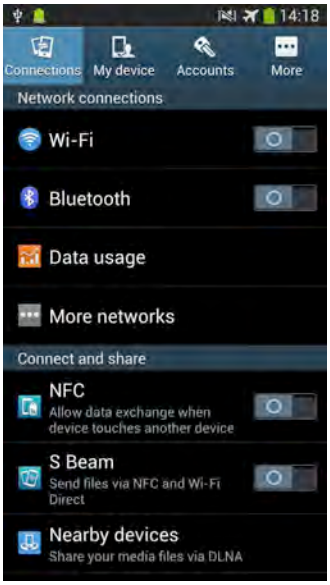



Figure 71

## Shutting Down

Pressing and holding the power button on the device will bring up the *Phone options* menu (**Figure 72a**). Select *Power off* from this prompt, and then select *OK* from the subsequent *Power off* prompt (**Figure 72b**).

Note: Tapping the power button will simply turn off the screen; it will not turn the mobile device completely off – the battery will continue to discharge.

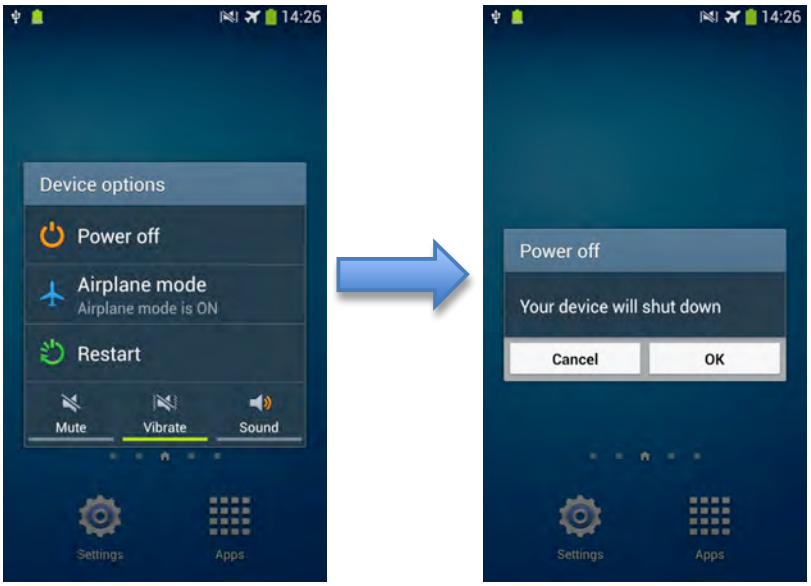
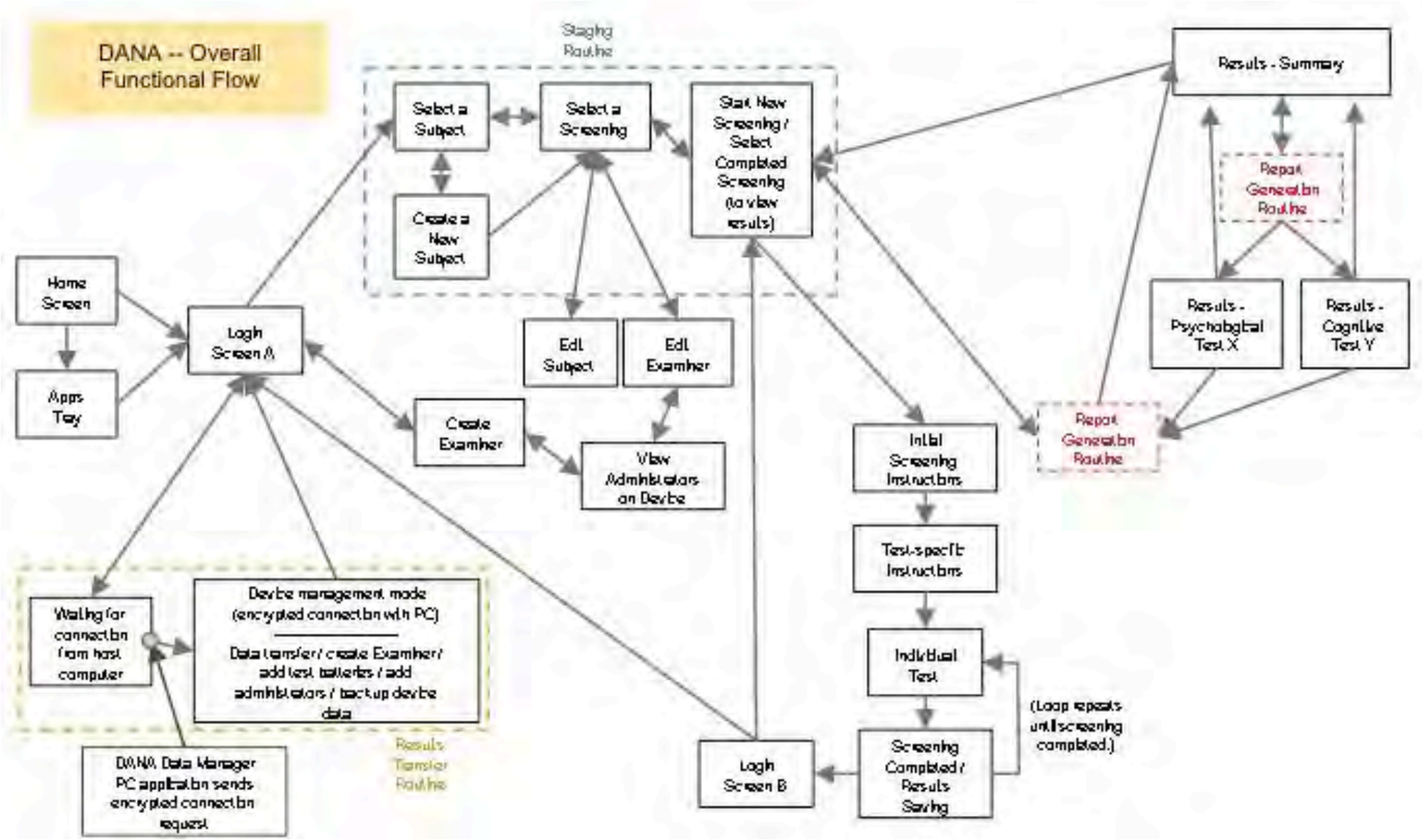
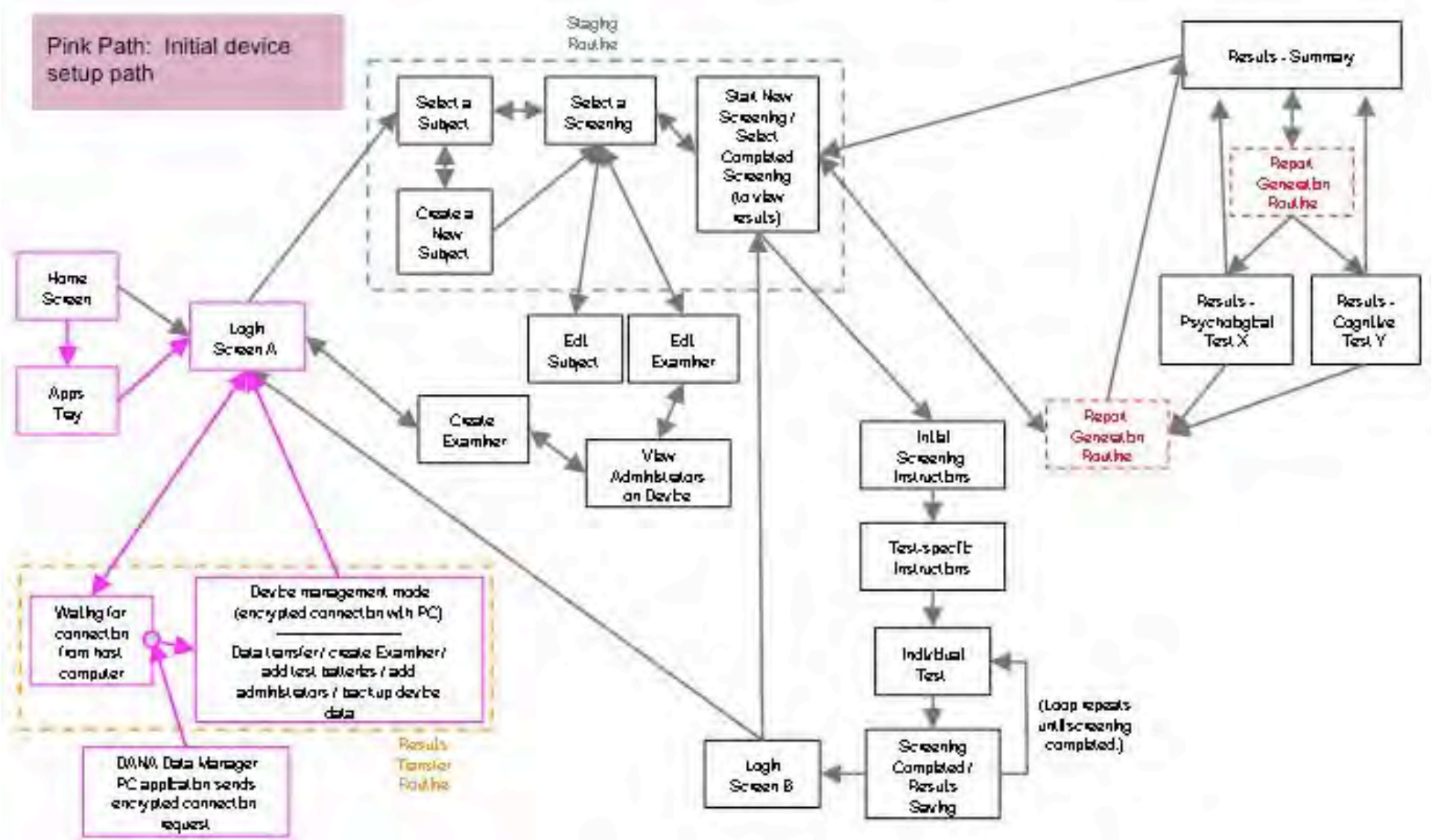
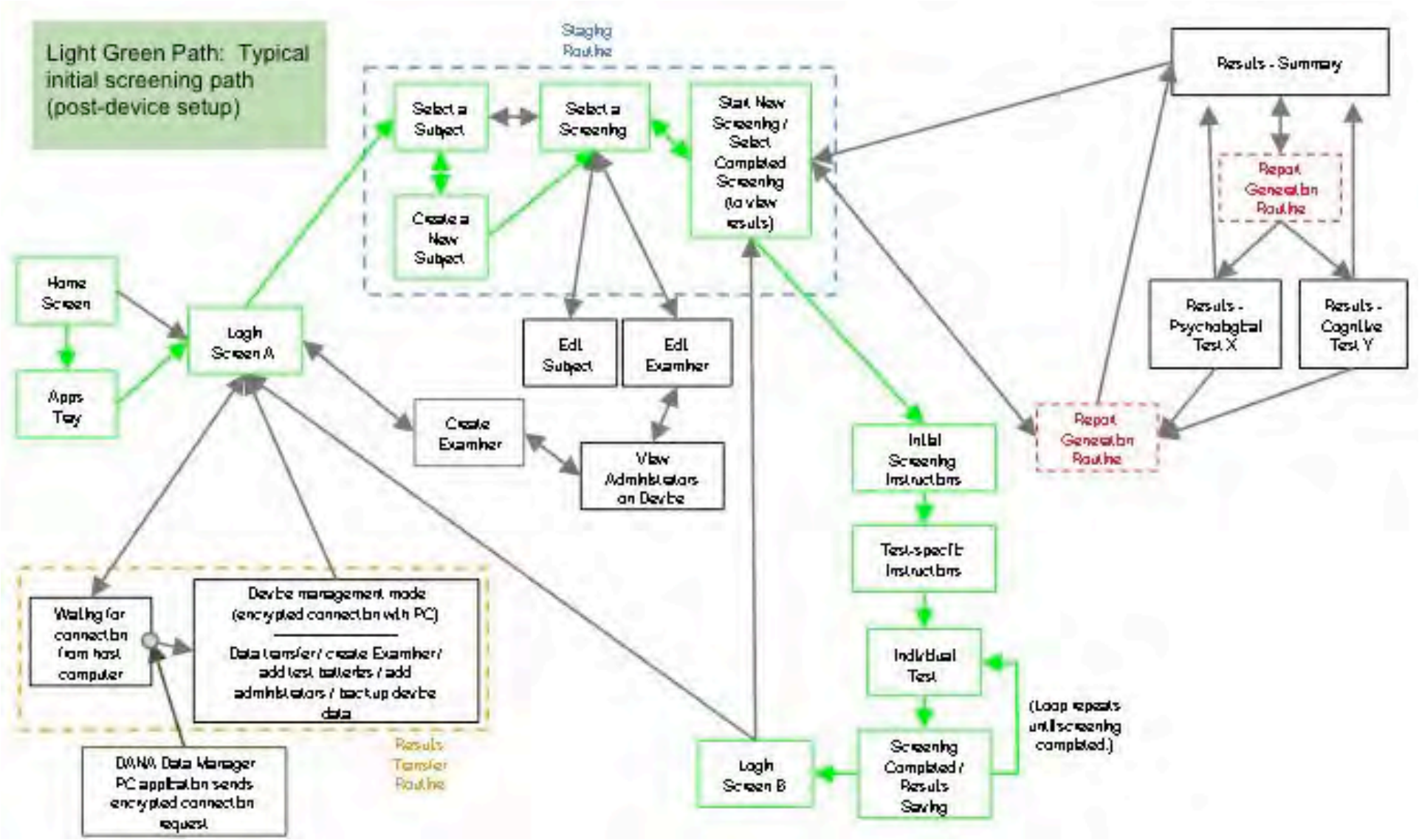


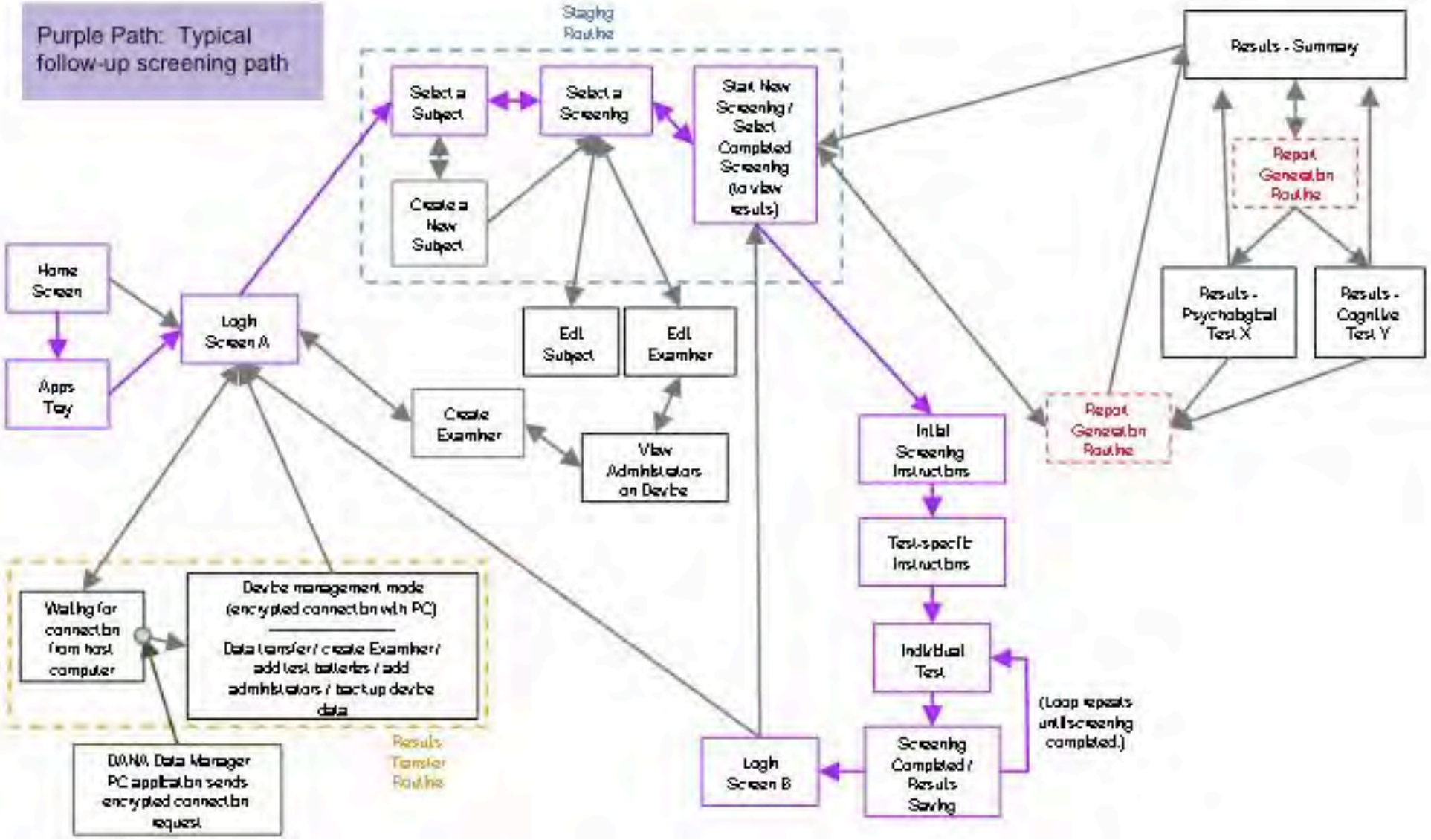

Figure 72a Figure 72b

# Appendix C – Detailed Flow of DANA




Pink Path: Initial device setup path
Staging Routine
Select a Subject
Select a Screening
Start New Screening / Select Completed Screening (to view results)
Create a New Subject
Results - Summary
Report Generation Routine
Results - Psychological Test X
Results - Cognitive Test Y
Home Screen
Apps Tray
Login Screen A
Edit Subject
Edit Examiner
Create Examiner
View Administrators on Device
Report Generation Routine
Initial Screening Instructions
Test-specific Instructions
Individual Test
(Loop repeats until screening completed.)
Screening Completed / Results Saving
Login Screen B
Waiting for connection from host computer
Device management mode (encrypted connection with PC)
Data transfer / create Examiner / add test batteries / add administrators / backup device data
DANA Data Manager PC application sends encrypted connection request
Results Transfer Routine


Light Green Path: Typical initial screening path (post-device setup)
Staging Routine
Select a Subject
Select a Screening
Start New Screening / Select Completed Screening (to view results)
Create a New Subject
Results - Summary
Report Generation Routine
Results - Psychological Test X
Results - Cognitive Test Y
Home Screen
Apps Tray
Login Screen A
Edit Subject
Edit Examiner
Create Examiner
View Administrations on Device
Report Generation Routine
Initial Screening Instructions
Test-specific Instructions
Individual Test
(Loop repeats until screening completed.)
Screening Completed / Results Saving
Login Screen B
Waiting for connection from host computer
Device management mode (encrypted connection with PC)
Data transfer / create Examiner / add test batteries / add administrators / backup device data
Results Transfer Routine
DANA Data Manager PC application sends encrypted connection request


Purple Path: Typical follow-up screening path
Staging Routine
Select a Subject
Select a Screening
Start New Screening / Select Completed Screening (to view results)
Create a New Subject
Results - Summary
Report Generation Routine
Results - Psychological Test X
Results - Cognitive Test Y
Home Screen
Apps Tray
Login Screen A
Edit Subject
Edit Examiner
Create Examiner
View Administrators on Device
Report Generation Routine
Initial Screening Instructions
Test-specific Instructions
Individual Test
(Loop repeats until screening completed.)
Screening Completed / Results Saving
Login Screen B
Waiting for connection from host computer
Device management mode (encrypted connection with PC)
Data transfer / create Examiner / add test batteries / add administrators / back up device data
Results Transfer Routine
DANA Data Manager PC application sends encrypted connection request

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# Appendix G: Opportunity Details

## DoD and IC Targets:

| Dept | Agency | Office / Program ID | Direct / Channel | Need | Contact | Justification |
|---|---|---|---|---|---|---|
| DHS | Coast Guard | | Direct | Servicemen safety | | 9/12 - 52,500 armed active duty, auxiliary and reservists. More than 7,000 Coast Guard members sustained a TBI between the years 2000 and 2012. |
| DHS | Customs and Border Protection | Workforce Health and Medical Support Division | Direct | Southern Border rocking | Douglas Rupard, Safety Manager, Division of Occupational Safety and Health, Customs and Border Protection, US Department of Homeland Security | 9/12 - 42,000 armed agents. While the total number of assaults on Border Patrol agents has been declining, physical assaults and assaults with rocks -- referred to as "rockings" by CBP -- have been risen since 2001. |
| DHS | Customs and Border Protection | | National Border Patrol Council | Employee/agent protection | Terrence Shigg, Health and Safety Director, National Border Patrol Council | 9/12 -This is the lobbying/union that represents the border patrol agents. |
| DHS | Federal Protective Service | | Direct | Employee safety | | |
| DHS | FEMA | Ready.gov | Direct | First responder (toolkits public side) | Darryl Madden, Director | 9/12 - Madden is meeting with acquisition teams to discuss discretionary funding streams. Need pricing information from Anthrotronix. 8/27 - Met with Madden FEMA has money available in O&M (Operations and Management) funds. |
| DHS | FEMA | Safety, Heath & Medical Readiness Division | Direct | Employee safety | Bronson Brown, Director, Safety, Heath & Medical Readiness Division, Federal Emergency Management Agency, US Department of Homeland Security | 9/12 - First responder TBI and fatigue testing |
| DHS | Immigration and Customs Enforcement | Office of Safety, Health and Environmental Management | Direct | Agent safety | | 9/12 - 18,000 armed agents. |

| Dept | Agency | Office / Program ID | Direct / Channel | Need | Contact | Justification |
|---|---|---|---|---|---|---|
| DHS | Immigration and Customs Enforcement | | Direct | Detainee safety | David McMillan, Medical Liaison Officer, Immigration and Customs Enforcement, US Department of Homeland Security | 9/12 - Recent ACLU actions against ICE for questionable detainee treatment. |
| DHS | Secret Service | | Direct | Employee safety | Randy Stair, Supervisory Emergency Services Specialist Program Manager, Emergency Services, US Secret Service, US Department of Homeland Security | 9/12 - 6,500 Secret Service agents currently employed. |
| DHS | TSA | Occupational Safety, Health, & Environment | Direct | | Jill Segraves, Director, Occupational Safety, Health, & Environment, Transportation Security Administration, US Department of Homeland Security | 9/12 - 14,600 armend TSA agents. |
| Intelligence Community | NSA | Environmental, Safety and Health Solutions Division | Direct | | Thomas Crawford, Chief, Environmental, Safety and Health Solutions Division, National Security Agency | |
| State | | Office of Safety, Health and Environmental Management | Direct | HAZMAT employee assessments | Wayne Quillin, Director, DASHO Operations Office, Office of Medical Services, US Department of State | 9/12 - DASHO includes Medical monitoring of employees assigned to hazardous workplaces. 9/2 - The Office of Safety, Health and Environmental Management (OBO/OPS/SHEM), the Domestic Environmental and Safety Division (A/OPR/FMS/DESD), the Designated Agency Safety and Health Official (DASHO), and the DASHO Operations Office (MED/DASHO) are responsible for the Department of State's Safety and Health Program. |

| Dept | Agency | Office / Program ID | Direct / Channel | Need | Contact | Justification |
|---|---|---|---|---|---|---|
| Veterans Affairs | | | Magellan | Vendor | | 9/12 - Since 2000, more than 250,000 service members — some still on active duty — have received diagnoses of traumatic brain injury, or T.B.I., according to the Defense Department. Though T.B.I. is commonly viewed as resulting from blast exposure, the vast majority of those injuries were diagnosed in nondeployed troops who were involved in vehicle crashes, training accidents or sports injuries. |
| Veterans Affairs | | | LifeCare, Inc. | Vendor | | |
| Veterans Affairs | | | American Veterans with Brain Injuries (VBI) | Policy | | 9/12 - AVBI (www.avbi.org) was organized in 2004 as a grassroots effort whose mission is to offer support to the families of American Service members and Veterans who have suffered brain injuries. |

## Other Federal Targets:

| Dept | Agency | Office / Program ID | Direct / Channel | Need | Contact | Justification |
|---|---|---|---|---|---|---|
| DOE | Office of Health, Safety and Security | Special Operations Division | Direct | DOE labs | Frank Celia, Director: Brenda Johnson, 202-586-6117 | 9/12 - SOD acts a liaison between DOE and Maintains active liaison with other federal law enforcement agencies to include the US Secret Service, Diplomatic Security Service, US Marshals, TSA, US Capitol Police, Federal Protective Service, and the Department of Homeland Security along with State and Local police departments and agencies. 9/4 -The program is supported by well trained and motivated experts providing executive protection operations, continuity support, investigative case management, intelligence dissemination, and protective logistics. |
| DOJ | FBI | | Direct | | David Wade, Chief Medical Officer, Federal Bureau of Investigation, US Department of Justice; William Fabbri, Director, Emergency Medical Support Program, | 9/10 - |

| Dept | Agency | Office / Program ID | Direct / Channel | Need | Contact | Justification |
|---|---|---|---|---|---|---|
| | | | | | Federal Bureau of Investigation, US Department of Justice | |
| HHS | | | Direct | Medical Standards and Clearance Programs | Marc Leffer, Chief, Medical Affairs/Strategic Development, Federal Occupational Health, US Department of Health and Human Services | 9/2 - Looking at clear and legally defensible fitness for duty standards and practices. |
| Interior | National Park Service | Security and Emergency Services / Forest fire fighting / Visitor and Resource Protection Division | Direct | Law enforcement, rangers / Search & rescue | Dean Ross, Deputy Chief, Law Enforcement, Security and Emergency Services, National Park Service, US Department of the Interior; Laurence Broun, Director, Office of Emergency Management, 202 208-3721, Laurence_Broun@ios.doi.gov; Lisa Branum Asst. Director, Preparedness and Response Division, 202 208-5673, Lisa_A_Branum@ios.doi.govBret Meldrum, Branch Chief, Visitor Use and Social Sciences Branch, Resources Management and Science Division, TEL: 209-379-1216, FAX: 209-379-1131, Bret_Meldrum@nps.gov; Jim Bacon, Jim Bacon, M.S. (Outdoor | 9/12 - Multiple opportunities within DOI ranger program, forest fighting teams and visitor search and rescue activities. |

| Dept | Agency | Office / Program ID | Direct / Channel | Need | Contact | Justification |
|---|---|---|---|---|---|---|
| | | | | | Recreation Planner with the NPS Denver Service Center stationed at Yosemite National Park), 209-379-1375 , | |
| Interior | | Occupational Health and Medical Programs | Direct | Mining policy | Bob Garbe, Chief, Division of Occupational Health and Medical Programs, Office of Occupational Safety and Health, US Department of the Interior | 9/12 - DOI runs the Office of Mine Safety. |
| Justice | Multiple | Federal Law Enforcement Training Facility (FLETC) | Direct | Agent safety | Eric Katz, Director Agent recovery; Mike Harrigan, Administrator | 9/12 - The Department of Justice was formerly the largest but remains the most prominent collection of law enforcement agencies, and handled most law enforcement duties at the federal level.[1] It includes the United States Marshals Service (USMS), the Federal Bureau of Investigation (FBI), the Drug Enforcement Administration (DEA), and the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), Federal Bureau of Prisons (BOP), and others. |

| Dept | Agency | Office / Program ID | Direct / Channel | Need | Contact | Justification |
|---|---|---|---|---|---|---|
| Justice | Multiple | | The Johns Hopkins Medical Institutions | Policy and medical oversight | Nelson Tang, Director, Division of Special Operations, Department of Emergency Medicine, Chief Medical Officer, Center for Law Enforcement Medicine, The Johns Hopkins Medical Institutions | 9/12 - Dr. Tang is the CMO for the Center for Law Enforcement Medicine |
| Multiple | OSHA | | Direct | Safety program policies | Mark Hagemann, Director, Office of Safety Systems, Occupational Safety and Health Administration | 9/12 - Head injury protection is a major OSHA concern. Hard hats were worn by only 16% of those workers who sustained head injuries. Potential commercial policy recommendations. |
| NGO | American Red Cross | Human Capital | Direct | Staff protection and post deployment support | Nancy Smith, Manager, Staff Deployment Center, American Red Cross | 9/2 - Assessment for Red Cross employees and support for US service members who experience long-term health problems that are sometimes prevalent after deployment, such as depression, Post Traumatic Stress and Traumatic Brain Injuries (TBI). |
| Smithsonian Institution | | Office of Safety, Health and Environmental Management | Direct | | Jules Duva, Associate Director, Occupational Health Services, Office of Safety, Health and Environmental Management, Smithsonian Institution | 9/12 - SI supports research efforts worldwide. |
| Transportation | FAA | ATC | ITT Exelis | Air Traffic Controller Fatigue assessments | Dr. Claudia Randolph, VP, Innovation - Advanced Information Systems, (703) 668-6060, claudia.randolph@exelisinc.com; Thomas Payne, Director, (703) 668-2023, thomas.payne@exelisinc.com; Kristina Peterman, Director | 9/12 - ITT Exelis is prime contract holder to FAA NextGen. |

| Dept | Agency | Office / Program ID | Direct / Channel | Need | Contact | Justification |
|---|---|---|---|---|---|---|
| | | | | | Business Development, (703) 668-6089, kristina.peterman@itt.com | |
| Transportation | FAA | | National Air Traffic Controllers Association (NATCA) | Policy | Paul Rinaldi, President | 9/12 - FAA will develop a Fatigue Risk Management System for air traffic operations. This management system will be designed to collect and analyze data associated with work schedules, including work intensity, to ensure that the schedules are not increasing the possibility of fatigue. Systems like these are commonly used in other areas of aviation to evaluate levels of risk. The FAA is also designing a comprehensive fatigue awareness and education training program for employees. |